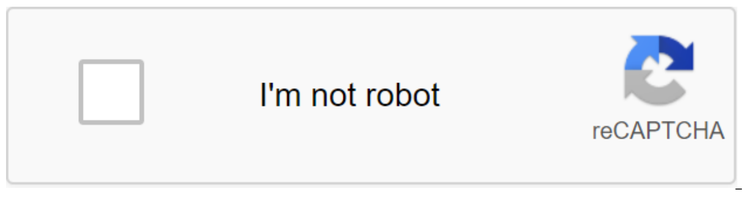
Risperdal consta bula pdf



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Risperdal Consta is effective in maintaining clinical improvement while maintaining treatment in patients who have submitted ... Risperdal Consta is effective in maintaining clinical improvement during supporting treatments in patients who submitted an initial response to oral risperidone treatment. Risperdal Consta is indicated to treat bipolar disorder type I alone. Risperdal Consta is indicated to treat maintaining bipolar disorder as an additional therapy in patients with bipolar disorder with frequent relapses. How does Risperdal work? Risperdal Consta is an antipsychotic drug, with controlled risperidone release formulation, for intramuscular use. As risperidone is released gradually into the body, you will only need one injection every 2 weeks. During the first 3 weeks of treatment, additional treatment with oral antipsychotic medication is required, as the first injection of Risperdal Consta has no immediate effect. Risperidone is a selective monoamine antagonist with specific properties. It has a high affinity for serotonergic receptors 5HT2 and dopaminergic D2. Risperidone also binds to alpha-1 adrenergic receptors and, at a lower affinity, to the adrenergic histaminergic receptors H1 and alpha-2. Risperidone has no affinity for cholinergic receptors. Although risperidone is a potent D2 antagonist, which is explained by improved positive symptoms of schizophrenia, it produces less depression of motor activity and induction of catalepsy than conventional antipsychotics. Balanced serotonergic and central dopaminergic antagonism can reduce the possibility of developing extrapyramidal side effects and expand therapeutic activity to negative and affective symptoms of schizophrenia. Risperdal ConstaDo does not use Risperdal Consta if you are allergic to this medicine or any component of its formula. Allergies can be recognized, for example, by skin rashes, itching, shortness of breath or swelling of the face. In case of any of these symptoms, see your doctor immediately. How to use Risperdal ConstaRisperdal Consta requires a lot of attention to step-by-step, described in usage mode to ensure proper administration and avoid difficulties in handling the kit. Long-release microspheres contained in the Risperdal Consta bottle should only be restored with dilution accompanying the package, and should be administered only with the appropriate needle, supplied in the kit, for glugle (2 inches) or deltoid (1 inch) administration. Don't replace any of the packaging components. Ensure full administration risperidone, all contents of the bottle must be entered. Partial introduction of contents can lead to a lower dose of risperidone. It is recommended to enter as soon as you recover. Remove the Risperdal Consta package from the fridge and wait until it reaches room temperature for about 30 minutes before recovering. Packaging contents: 1 vial of ampoules with risperidone injectable powder; 1 device (SmartSite) to assist in recovery;1 filled syringe containing a deminant for recovery;2 needles for use in the patient. 21G UTW 1 inch needle for deltoid administration and 20G TW 2 inch for administration in the glute region. Remove the colored plastic lid from the Risperdal Consta bottle. Do not remove the grey rubber lid. Clean it with alcohol and wait to dry. Open the SmartSite packaging and remove it by holding between the white end and the protective cover. Under no circumstances should you touch the metal end. It is very important that the SmartSite device fits correctly in the bottle, as it can be thinner during transfer to the bottle. Attach the bottle to a hard surface. Hold the base of the bottle. Orient the SmartSite access device without needles vertically over the bottle, so that the punch tip is in the center of the rubber bottle lid. Tap the end of the SmartSite impact device through the rubber lid of the vials bottle until the device snaps securely. CorrectIncorrectHold the base of the vial and disinfect the connection point (blue circle) of the SmartSite device with alcohol and wait to dry before attaching the syringe to the device. The filled syringe has a white tip consisting of two parts: a white ring to block the piston and a smooth white beanie. To open the syringe, hold it by the white ring and break the white lid of the syringe, breaking it (Don't rotate or cut the white hat). Remove the white lid with the tip of the inner rubber. For all the steps of the syringe mounting, keep it only with a white ring located on its tip. Holding a white ring will help prevent it from standing out and ensures that it stays connected to the syringe. Be careful not to tighten the components during installation. Excessive tightening of the joints can cause the parts to come out of the syringe. Holding the white syringe ring, insert and press the tip of the syringe into the blue circle of the SmartSite device and turn clockwise to make sure the syringe fits securely into the device (avoid turning the syringe more than necessary). Keep the SmartSite protective cover while docking to prevent it from rotating. Put the overall contents of the thinner syringe into the bottle. Shake at least 10 seconds (holding the piston rod down with your thumb). The mixture will be completed when the suspension is homogeneous, thick, milky and the powder is completely dispersed. The microspheres will be visible in the liquid, but there will be no drought. Do not store the bottle after recovery, as the suspension will be deposited. Reverse assembly and slowly vacuum the entire suspension with a syringe. Highlight part of the label on the shredded line and glue it to the syringe to identify it. Holding a white needle ring, disconnect the syringe from the SmartSite.Discard device with a bottle and device properly. Open the bag and take the appropriate needle, provided in the set. Do not touch the needle joint, just the transparent part of the needle cover. For control in the Gluteus area, select a 20G TW 2 inch needle (the longest needle with a yellow connector). For administration in the Deltoid region, select 21G UTW 1 inch needle (short needle with green connector). To prevent contamination, be careful not to touch the orange connector of the security device. Holding the white syringe ring, attach the orange connector to the syringe, gently turning clockwise. Keeping the white needle ring tight, hold the transparent tip of the needle and place it firmly on the orange protective device by pressing it and turning it clockwise. Installing a needle will provide a safe link between the needle and the orange safety device during all next steps. Re-occurring Risperdal Consta will be necessary before administration, because, over time, precipitation will occur after the

recovery of the drug. Shake vigorously for as long as necessary to re-overspend the microspheres. By keeping the white needle ring tight, remove the transparent needle cover without twisting as the needle can come out of the protective device. Do not rotate the lid, as the connector may be freed. Press the syringe lightly so that the air bubbles rise to the surface. Remove the air from the syringe, carefully and slowly tightening the piston while keeping the needle upright. Immediately insert the overall contents of the syringe intramuscularly into the patient's glute-deltoid muscle. The injection of the buttocks should be done in the upper outer quadrant of the glute area. Do not inject intravenously. Warning: To avoid injury with a contaminated needle: Do not use one hand to press the safety device on the needle; Don't try to disassemble your security device intentionally; Do not try to unearth a needle or rig a safety device if the needle is bent or damaged; Don't misuse your security device because can even design the device's needle. After the injection, press the needle into the orange safety device using a technique with one method. Perform the technique to one side, gently pressing the orange safety device to the flat surface. As the tool is pressed, the needle will be fastened firmly to it. Visually confirm that the needle sits completely inside the orange security device before discarding. Discard the needle properly. Also discard another needle (unused) provided in the kit. Not reuse: Medical devices require material characteristics to act as planned. These characteristics have only been tested for one use. Any attempt to recycle the device for later reuse could have a negative impact on the device or lead to poor performance. DosingAdults The recommended dose is 25 mg with intramuscular injection every two weeks. Some patients may benefit from large doses of 37.5 mg or 50 mg. Doses of more than 50 mg for two weeks are not recommended. Your doctor may prescribe oral Risperdal within the first 3 weeks after the first injection. The dose should not be increased more often than once every 4 weeks. The effect of dose adjustment should not be expected until 3 weeks after the dose increase. Your doctor will decide what the best dose is for you. The recommended dose for older patients is 25 mg with intramuscular injection every 2 weeks. Patients with renal or liver failureRisperdal Const was not studied in patients with liver and kidney problems. If you have one of these conditions, the recommended dose is to start treatment of 0.5 mg of risperidone, orally, twice a day, during the first week. In the second week, 1 mg can be given twice a day or 2 mg once a day. ChildrenRisperdal Consta was not evaluated in patients under the age of 18. Stopping treatment does not stop treatment without the knowledge of the doctor. Patients with schizophrenia may discontinue treatment of Risperdal Const for several reasons. Doctors should choose later antipsychotic treatments based on a reassessment of the patient's clinical condition and risk and benefit analysis. It should be noted that Risperdal Consta plasma concentrations are present in the patient for about 4-6 weeks after the last injection. Therefore, doctors should consider this fact, in addition to the level of symptoms of the patient before deciding on the dose and when to start any alternative antipsychotic therapy, after discontinuing Risperdal Consta.Follow your guide always observes the schedules, doses and duration of treatment. Do not stop the medicine without the doctor's knowledge. What if I forgot to use Risperdal Consta? If you miss an injection, see your doctor as it should be given as soon as possible. If in doubt, seek advice from your pharmacist or doctor or dentist. Risperdal ConstaPrecautionsStudies in elderly patients with dementia have shown that Risperdal is administered alone or with furosemid associated with higher mortality. Tell your doctor if you are taking furosemide. Furosemide is a drug used to treat high blood pressure, some heart problems or swelling of body parts by accumulating excess fluid. There was no increase in mortality among patients receiving other diuretics associated with risperidone. Regardless of treatment, dehydration is a common risk factor for mortality and should therefore be carefully avoided in older patients with dementia. Older patients with dementia experience sudden changes in mental state, sudden weakness or paralysis of the face, arms or legs, especially on the one hand, or cases of slurred speech. If any of these symptoms occur, even within a short time, seek medical attention immediately. Using Risperdal Consta with medications to treat high blood pressure can lead to a drop in blood pressure. Therefore, if you need to use Risperdal Consta and medication to lower your blood pressure, see your doctor. Tell your doctor if you or anyone in your family has a history of blood clots. These clots were found in the lungs and legs of patients using Risperdal Consta. Blood clots in the lungs can be fatal. If you have never taken Risperdal Consta, you should start treatment orally to test your tolerance to the drug before using Risperdal Consta.During long-term treatment, Risperdal Consta can cause involuntary muscle movements (dyskinesia retention), predominantly on the face. If this happens, see your doctor. Very rarely can there be a state of mental confusion, low level of consciousness, high temperature and muscle contractions (malignant neuroleptic syndrome). In this case, medical care should be requested urgently. As dangerously low amounts of a certain type of white blood cell needed to fight infections in the blood have been observed very rarely in patients treated with Risperdal Consta, your doctor should check your white cell count. Tell your doctor if you know you've had low white cell levels in the past may or may not be caused by other medications). Increased blood sugar levels were reported very rarely. See your doctor if you experience symptoms such as excessive thirst or an increased desire to urinate. Risperdal Consta should be used with caution if you have heart problems, especially irregular heart rate and abnormalities in the electrical activity of the heart (long-range RT syndrome) or if you are using medications that can alter the electrical activity of the heart. In these cases, the product should be used only after consultation with a doctor. During eye surgery, clouding the lens (cataract), the pupil (black circle in the middle of the eye) can not increase in size as needed. In addition, during surgery, the iris (colored part of the eye) can become sluggish, causing eye damage. Some medications (alpha-adrergic blockers) cause a long and painful erection of the penis, as was also reported with Risperdal during post-marketing observation. Risperdal has an antithetical effect (vomiting inhibition) that can mask the effects and symptoms of overdose with certain medications or conditions such as intestinal obstruction, Reye syndrome and brain tumor. As with other antipsychotics, Risperdal should be used with caution in patients with a history of seizures or other conditions that potentially lower the seizure threshold. Therefore, tell your doctor if you have or have had seizures in the past or other conditions that potentially lower the seizure threshold. Antipsychotic agents can jeopardize the body's ability to lower the temperature of the nucleus. Therefore, tell your doctor if you are performing intense exercise, expose yourself to intense heat, perform activities that cause dehydration or make the attendant use of medications with cholinergic activity. Allergic reactionsDard, if you have suffered oral risperidone, allergic reactions can occur very rarely after injections Risperdal Consta. Seek immediate medical attention if you experience a rash, swelling of the throat, itching or breathing problems, as these may be signs of a severe allergic reaction. Weight gainTrie is moderately like Risperdal Consta can cause weight gain. Cardiovascular disease, diabetes, Parkinson's disease, Levi's body dementia or EpilepsyTell are your doctor if you have one of these diseases. Careful medical supervision may be required during treatment with Risperdal Consta and the dosage may have to be adjusted. Renal or liver failure To tell the doctor if have one of these conditions. There is no experience of using Risperdal Consta in patients with impaired kidney or liver function. Older patients should be treated with the lowest dose (25 mg) of Risperdal® Const.CrianasTam has no experience using Risperdal Consta in patients under the age of 18. The effect on your ability to drive and drive can affect your attention or ability to drive. During treatment, you should not drive or drive cars before your doctor evaluates you, as your abilities and attention may be impaired. Pregnancy and breastfeedingPregnancyTell your doctor if you are pregnant or about to get pregnant. It will decide whether or not you can use Risperdal Consta.AmamentaTell your doctor if you are breastfeeding. Risperdal Const should not be used during breastfeeding. Tremors, muscle stiffness and/or weakness, drowsiness, arousal, breathing problems and feeding difficulties may occur in newborn mothers who used Risperdal Consta in the last trimester of pregnancy. This medication should not be used by pregnant women without medical or surgeon guidance. Accompanying taking with other substances Tell your doctor if you are taking any other medications. It will decide which medications you can use with Risperdal Consta.Risperdal Consta may interfere with the action of some drugs used to treat Parkinson's disease (dopamine agonists such as levodope). If you are taking high blood pressure medications, consult your doctor, as taking these medications with Risperdal Consta can cause your blood pressure to drop too much. Risperdal Consta should be used with caution when used with medications that alter the electrical activity of the heart, such as the following, among other things: malaria medications, heart rhythm disorders, allergies, other antipsychotics, antidepressants, diuretics or other medications that affect electrolytes in the body (sodium, potassium, magnesium). Some medications, when taken with Risperdal Consta, may increase or decrease the level of Risperdal Consta in the blood. Therefore, tell your doctor if you start or discontinue the use of the following drugs, as it may be necessary to adjust the dose: Medications that may increase the level of Risperdal Consta in the blood: Fluoxetine and paroxetine, medications mainly used in the treatment of depression and other anxiety disorders; Itrakonazole and ketoconazol, medications for the treatment of infections caused by fungi; Some drugs used in the treatment of AIDS, such as ritonavir; Verapamil, a drug used to treat high blood pressure and/or Hearts; Sertraline and fluvoxamine, medications used to treat depression and other mental disorders. Medications that can reduce the level of Risperdal Consta in the blood: Carbamazepine, a drug used primarily for the treatment of epilepsy or trigeminal neuralgia (severe bouts of pain on the face); Richampicin, a medicine for the treatment of some infections. It is unlikely that the following drugs will change the effect of Risperdal Consta:Cimetidine and ranitidine, two medications to reduce stomach acidity, may slightly increase the amount of Risperdal Consta in the blood, but it is unlikely that they can change the effects of Risperdal Consta; Erythromycin, an antibiotic, does not affect the level of Risperdal Consta in the blood; Topiramate, a drug used to treat epilepsy and migraine, has no significant effect on Risperdal Consta levels in the blood; Galantamine and dopezil, the drugs used in the treatment of dementia, have no effect on Risperdal Consta.It is unlikely Risperdal Consta will change the effect of the following drugs: Risperdal Consta does not seem to interact with lithium or valproate, two medications used in the treatment of mania, or digoxin, a cure for the heart. Interaction with alcoholRisperdal Consta can enhance the effects of alcohol and drugs that reduce the ability to react (tranquilizers and some types of powerful analgesics, antihistamines and antidepressants). So don't take alcoholic beverages and avoid other medications using them only if they are prescribed by the doctor. Tell your doctor or dentist if you use any other medications. Do not use medication without the knowledge of a doctor. It can be dangerous for your health. Adverse reactions Risperdal ConstaThroughout this point, adverse reactions are presented. Adverse reactions are side effects that have been deemed reasonably associated with the use of risperidone on the basis of a comprehensive assessment of available information on adverse events. Like all medications, Risperdal Consta can cause adverse effects. Adverse reactions associated with treatment with Risperdal Consta are listed below. If you have any of these symptoms, see your doctor. Clinical studiesA data below we will list the adverse reactions observed in clinical studies with Risperdal Consta administration in patients with schizophrenia and for adjuvant-supporting treatment of patients with bipolar disorder I (who also received various mood stabilizers, antidepressants and/or anxiolytics) and in monotherapy to maintain the treatment of bipolar disorder I. Most reactions were mild to moderate severity. Patients with after adverse reactions were reported ≥ 2% of patients treated with Risperdal Consta: Infections and Infection: Upper Respiratory Tract Infections. Nervous system disorders: Headache, Parkinson's (slow or compromised movement, feeling stiff or strained muscles, Other signs of Parkinson's include slow and scrambled walking, resting tremors, increased saliva and/or drooling, and loss of facial expression, dizziness, acatisia (inability to stay put, motor anxiety and feeling muscle tremor), drowsiness, tremor, sedia, syncopation, and loss of facial expression, and loss of facial expressions. Ophthalmological disorders: blurred vision. Respiratory, thoracic and mediatinal disorders: cough, sinus congestion. Disorders of the gastrointestinal tract: constipation, dry mouth, dyspepsia, nausea, toothache, saliva hypersecretation (excessive saliva secretion). Skin and subcutaneous tissue disorders: acne, dry skin. Disorders of musculoskeletal and connective tissues: pain in the limbs. General disorders and conditions on the administration's website: fatigue, astin (weakness), peripheral swelling, pain, fever. Tests: Weight gain, weight loss. Parkinson's includes: extrapyramidal disorder, musculoskeletal brain, muscle stiffness and bradylines. Acatisia includes: acatisia and agitation. The following adverse reactions were reported ≥ 4% of patients who received adjuvant treatment with Risperdal Constaa: Infections and Infections: Upper Respiratory Tract Infections. Metabolic and eating disorders: decreased appetite, increased appetite. Nervous system disorders: tremor, Parkinson's, dinesiab (involuntary muscle movements that may include repetitive, spastic or curved movements or curvature), sowing, attention disorder. Respiratory, thoracic and mediatinal disorders: cough. Musculoskeletal and connective tissue disorders: Artralgia (joint pain). Reproductive system and breast disorders: Amenorrhea (lack of menstruation). General unrest and conditions in place of the administration: abnormal gait. Tests: Weight gain.a Patients who received Risperdal Consta or a placebo in a double-blind manner in addition to their previous treatment, which included mood stabilizers, antidepressants and/or anxiolytics.bParkinsonism includes: muscle stiffness, hypokinesis, serrated wheel stiffness, and bradykinesia. Dyskinesia includes: muscle contraction and dyskinesia. Other Clinical Research DataA we will list additional adverse reactions observed in patients with schizophrenia, treatments in clinical studies with and/or paliperidone (a compound resulting from the metabolism of risperidone). The following additional adverse reactions have been reported with risperidone and/or paliperidone ≥ 2% of patients with schizophrenia treatment Risperdal Consta: Psychiatric disorders: Excitation, anxiety, depression, insomnia. Nervous system disorders:Acatisia, Parkinson's.Heart Disorders:Takiccardia (rapid heartbeat). Respiratory, thoracic and mediatynous disorders: nasal congestion. Gastrointestinal disorders: abdominal discomfort, diarrhea, vomiting. Skin and subcutaneous tissue disorders:Rush. Disorders of connective and musculoskeletal tissue: back pain, muscle spasms, pain in musculoskeletal disease. General Disorders and Conditions on the Administration's website: Edema. Insomnia includes: initial insomnia, average insomnia; Acatisia includes: hyperkinesis (involuntary and frequent movement), restless leg syndrome, anxiety; Parkinson's includes: skinnesia, bradynesia, cog intercession, hyper-syllia (excessive saliva secretion), extrapyramidal symptoms, abnormal glabella reflex, muscle stiffness, muscle tension, musculoskeletal joint. Swelling includes: generalized swelling, peripheral swelling, depressive swelling. The following adverse reactions were reported with risperidone and/or paliperidone lt; 2% of patients with schizophrenia are treated with Risperdal Consta.Infections and infestations: Ear infection, infection, flu, sinusitis. Disorders of the immune system:Hypersensitivity (allergy). Metabolic and eating disorders: Decreased appetite, increased appetite. Psychiatric disorders: Confusion of the condition, decreased libido, nightmare. Nervous system disorders: postural dizziness, dysarthria (speech difficulty), dyskinesia, paraesthesia (tingling, twinselning or numbness of the skin). Ophthalmological Disorders:Photophobia (painful hypersensitivity to light). Ear and Maze Disorder: Earache. Heart disorders: Bradycardia (slow heartbeat), conductivity disorder, abnormal electrocardiogram, electrocardiogram with long-term CT, rapid heartbeat (perception of heartbeat). Respiratory, thoracic and mediatin disorders: shortness of breath (shortness of breath), pharyngolaring pain, wheezing. Hepatobiliary disorders: Increased gamma-glutamyltransferase, increase in liver enzymes. Skin and subcutaneous tissue disorders: itching, seborroid dermatitis, skin diseases. Disturbances of the connective and musculoskeletal brain: joint stiffness, muscle weakness. Urinary and urinary tract disorders: urinary incontinence. Reproductive system and breast disorders: breast discomfort, ejaculation disorder, erectile dysfunction, galactorroy (abnormal milk production). Disorders Conditions in place of administration: discomfort in the chest, abnormal sensations, reaction at the injection site. The following adverse reactions have been reported with risperidone and/or paliperidone in other clinical studies, but have not been reported by patients with schizophrenia treatment Risperdal Consta (25 mg or 50 mg): Infections and invivation: Acarodermatitis (skin inflammation, caused by ticks), bronchitis, cellulite, cystitis (inflammation of the bladder), eye infection, localized infection, onychomicosis (mycosis in nails), pneumonia, respiratory infection, subcutaneous abscess, tonsillitis (tonsillitis), urinary tract infection, viral infection. Disorders of the blood and lymphatic system: anemia, an increase in the number of eosinophils, a decrease in hematocrit, neutropenia, a decrease in the number of white blood cells. Disorders of the immune system: Anaphylactic reaction (severe allergic reaction, which leads to difficulty breathing and shock). Endocrine Disorders: The presence of glucose in the urine, hyperprolactinemia (excessive prolactin secretion, symptoms of which may include, in men, breast swelling, difficulties in obtaining or maintaining or other sexual dysfunction, and in women lack of menstrual cycles or other problems with the menstrual cycle). Metabolic and food disorders: anorexia (loss of appetite), elevated cholesterol levels in the blood, increase in blood triglycerides, hyperglycemia (increased blood sugar), hyperinsulinemia (increase of insulin in the blood), polydipdia (excessive thirst). Mental disorders: anorgasmia (inability to reach orgasm), affective dulling (difficulty in expressing emotions and feelings), sleep disorder. Nervous system disorders: balance disorder, stroke (sudden loss of blood supply to the brain), cerebral vascular disorder (problems in the blood vessels of the brain), convulsions, convulsions, abnormal coordination, decreased level of consciousness, diabetic coma (coma due to uncontrolled diabetes), dystonia (slow and prolonged involuntary muscle contractions, including abnormal movements of the eyes, mouth, tongue or jaw), head instability, loss of consciousness, malignant neuroleptic syndrome (confusion, decreased or loss of consciousness), high temperature and severe muscle dry eyes, eye movement disorder, oculopia crisis (spastic eye movement in a fixed position, usually upwards), crust on the edge of the eyelids, glaucoma (increased pressure inside the eyeball), enlargement of rupture, eye hyperemia (reddish eye). Ear and maze disorders: tinnitus, dizziness. Heart disorders: Atrioventricular block (cessation of conduct between the upper and lower parts of the heart), orthostatic postural tachycardia syndrome, sinus arrhythmia. Vascular disorders: flushing (redness), hypotension (low pressure), orthostatic hypotension (low pressure when standing). Respiratory, thoracic and mediatinal disorders: dysphonia (ochriplity), epistaxis (nosebleeds), hyperventilation, aspiration pneumonia, pulmonary congestion, ralyzin (noisy breathing), respiratory disorders, respiratory problems, respiratory congestion. Disorders of the gastrointestinal tract: heilitis (erythema and ulcer in the corner of the mouth), dysphagia (difficult swallowing), fecal urinary incontinence, fephaloma (hardened stool), flatulence (gas), gastroenteritis, intestinal obstruction, swelling of the tongue. Hepatobiliary Disorders: Increased transainase. Skin and subcutaneous tissue disorders: drug eruption, eczema, erythema (skin redness), hypervatosis (skin hardening), skin discoloration, skin damage, hives. Connective tissue, muscle and bone disorders: Increased blood phosphonin creatine, joint swelling, neck pain, abnormal posture, rhabdomyolysis (destruction of muscular fibers and muscle pain). Urinary and urinary tract disorders: dysuria (difficulty or pain when urinating), polishing (frequent urination with a small volume). Reproductive system and breast disorders: breast secretion, breast engorment, breast enlargement, breast augmentation, gynecomastia (breast growth in men), menstrual disorder, delayed menstruation, sexual dysfunction, vaginal secretion. General disorders and conditions at the site of administration: decreased body temperature, fever, chills, discomfort, withdrawal syndrome (withdrawal of the drug), swelling of the face, hardening, malaise, cold in the limbs, head of the limb. Injuries, poisonings and postural complications: Fall, pain procedure. Dystonia includes: blepharospasm (involuntary contractions of the eyelids), cervical spasm, emprostotone (tetanus spasm that bends the body forward), facial spasm, hypertension (extreme muscle tension), laryngospasm, involuntary muscle contractions, myotonia (reduced muscle relaxation rate), oculogira crisis, opistoistotone pleorototono (tetanus spasm that bends the body to one side), sardonic laughter, tetani, tongue paralysis, tongue spasm, toricolis, trismus (painful contracture of the jaw muscles). Management includes: irregular menstruation, oligomenorrhea (infrequent or very light menstruation). Post-marketing dataAdverse reactions observed with risperidone and/or paliperidone during the experiment after the start of Risperdal Consta marketing are described below. A very rare reaction (found in less than 0.01% of patients using this medication), including isolated reports: Blood and lymphatic disorders: Agranulocostosis, thrombocytopenia (reduction of thrombocytes, blood cells that help in stopping bleeding). Endocrine Disorders: Inappropriate secretion of the antidiuretic hormone (hormone, urine volume control). Metabolic and nutritional disorders: diabetes mellitus, diabetic ketoacidosis (complications of uncontrolled diabetes, which can lead to death), hypoglycemia (reduced blood sugar), water poisoning. Psychiatric Disorders:Mania (increased mood). Nervous system disorders: Diggeusia (decreased taste). Ophthalmological Disorders: Retinal Ortery Oclusia, Volhyan toffee Syndrome (Intraoperation), a condition that can occur during cataract surgery in patients who use or have already used Risperdal.Heartdiac Disorder: Atrial Fibrillation (abnormal heart rate). Vascular disorders: deep vein thrombosis (blood clots in the legs), pulmonary embolism (blood clots in the lungs). Respiratory, thoracic and mediatinal disorders: sleep apnea syndrome (difficult breathing during sleep). Gastrointestinal disorders: pancreatitis (inflammation of the pancreas), yl (obstruction of the intestine). Hepatobiliary disorders: jaundice (yellow skin and eyes). Diseases of the skin and subcutaneous tissue: alopecia (hair loss), angioedema (severe allergic reaction characterized by fever, swelling of the mouth, face, lips or tongue, shortness of breath, itching, rash, and sometimes drop in blood pressure). Urinary and urinary tract disorders: urinary retention. Pregnancy, Puerperium and perital conditions: neonatal abstinence syndrome (drug withdrawal syndrome that occurs in newborns). Reproductive system and breast disorders: priapism (long and painful erection of the penis). Common disorders: Hypothermia (decreased body temperature), injection site reaction, including abscess; cellulite, cyst, hematoma, necrosis, ulcer. Very rare cases of anaphylactic reactions after the use of Risperdal Consta have been reported in the post-marketing period, during the who had a preliminary tolerance to oral risperidone. Tell your doctor, dentist or pharmacist the appearance of adverse reactions using the drug. Also inform the company through your customer service.Composition From Risperdal ConstaRisperdal Consta 25 mg: Each bottle contains 25 mg of risperidone. Excipient: lactation-coglycolipid polymer. Risperdal Consta 37.5 mg: Each bottle contains 37.5 mg of risperidone. Excipient: lactation-coglycolipid polymer. Risperdal Consta 50 mg: Each bottle contains 50 mg of risperidone. Excipient: lactation-coglycolipid polymer. Each dilutor syringe contains: Anhydrous citric acid, injection water, sodium carmelose, sodium chloride, sodium dibasic phosphate, sodium hydroxide and polysorbat 20.Overdose Of Risperdal ConstaAlthough overdose is less likely with parenteral administration than with oral, information about oral overdose is provided. Risperdal Consta should be administered by a medical professional by gluteal or deltoid injection, not by the patient, as in the case of oral treatment. Therefore, in these conditions, the risk of overdose of Risperdal Const is considered insignificant. Signs and symptomsIn the unlikely case of an overdose Risperdal Consta should be administered, one or more of the following symptoms may occur: decreased attention, drowsiness, excessive tremor, excessive muscle stiffness, change of heart rate and decreased blood pressure. Cases of abnormalities in cardiac electrical conduction (extension of interval) and convulsions have been reported. An overdose can occur if you take another medication with Risperdal.Seek your doctor if you experience any of the above symptoms. TreatmentIn case overdose, the doctor should set and keep your airways open if you are unconscious. In addition, if your blood pressure is low, your doctor will manage agents called sympathomimetics. Finally, your doctor will monitor the electrical activity of your heart. If you use a large amount of this medication, quickly seek medical attention and take a package or package of leaflets of the drug if possible. Call 0800 722 6001 if you need an additional guide. Drug interaction Risperdal ConstaInteractions associated with pharmacodynamicsDrugs with central action and alcoholIn connection with its primary effects on the central nervous system, Risperidone (active substance) should be administered with caution in combination with other drugs with central action or alcohol. Levodopa and dopamine agonists Risperidone (active substance) can antagonize the effect of levodopa and other dopamine agonists. Drugs with effect Clinically significant was noted after marketing, with the concomitant use of Risperidone (active substance) and antihypertensive treatment. Drugs that extend the interval to RT are recommended when prescribing Risperidone (active substance) with drugs that are known to prolong the RT interval. Interactions associated with pharmacokinetics inhibitorsPotent CYP2D6Concomitant administration of risperidone (active substance) and powerful INHIBITOR CYP2D6 may increase the concentration in plasma of risperidone (active substance), but less than the active apsiotic fraction. Higher doses of the powerful CYP2D6 inhibitor may increase the concentration of the active antipsychotic fraction of risperidone (active substance) (e.g. paroxetine). When paroxetine or other powerful CYP2D6 inhibitor, especially in high doses, has started concomitant or discontinued, the doctor should reconsider the dosage of Risperidone (active substance). Cyp3A4 and/or P-gpA inhibitors concomitantly administering Risperidone (active substance) and a powerful CYP3A4 inhibitor and/or P-gp can significantly increase plasma concentration of the active antipsychotic fraction of risperidone (active substance). When the concomitant administration of itrakonazole or other powerful CYP3A4 and/or P-gp inhibitor is initiated or discontinued, the doctor should reconsider the dosage of Risperidone (active substance). CyP3A4 and/or P-gpA induction of Risperidone (active substance) and the powerful CYP3A4 and/or P-gp inductor can reduce plasma concentration of the active antipsychotic fraction of Risperidone (active substance). When the concomitant administration of carbamazepine or other powerful CYP3A4 and/or P-gp inductor is initiated or discontinued, the doctor should reconsider the dosage of Risperidone (active substance). Drugs with high protein bindingWhen Risperidone (active substance) is taken with drugs with a high protein binding index, in any of them there is no displacement of clinically significant plasma proteins. When these medications are administered accompanying, consult with their flyers about the metabolic pathway and the possible need to adjust doses. Pediatric populationInteractions were conducted only in adults. The relevance of the results of these studies for pediatric patients is unknown. Examples of drugs with the potential for interaction or that did not interact with Risperidone AntibacterialSErythromycin, a moderate inhibitor of CYP3A4, do not alter the pharmacokinetics of risperidone (active substance) and active antipsychotic fraction. Richampicin, a strong CYP3A4 inductor and P-gp inductor, decreased risperidone (active substance) and active antipsychotic fraction. Inhibitors of cholinesterase galantamine and dopesil, like CYP2D6 and CYP3A4 substrates, have not shown clinically significant effects on Risperidone pharmacokinetics (active substance) and active antipsychotic fraction. Antiepileptic carbamazepine, a strong inductor cyP3A4 and P-gp inductor, reduces plasma levels of the active antipsychotic fraction of risperidone (active substance). Topiramate slightly reduced the bioavailability of risperidone (active substance), but not the active antipsychotic fraction. Thus, this interaction probably does not represent clinical significance. Risperidone (active substance) does not show a clinically significant effect on the pharmacokinetics of valproate or topiramate. Antifungalitracrazole, a strong CYP3A4 inhibitor and P-gp inhibitor at a dose of 200 mg/day, increased the plasma concentration of the active antipsychotic fraction by about 70%, with doses of risperidone (active substance) 2 mg/day to 8 mg/day. Ketoconazole, a strong CYP3A4 inhibitor and P-gp inhibitor at a dose of 200 mg/day, increased concentrations in risperidone plasma (active substance) and reduced plasma concentrations of 9-hydroxy-risperidone (active substance). Antipsychotic phenothiase may increase the concentration in plasma of risperidone (active substance), but not the active antipsychotic fraction. Aripiprazole, substrate CYP2D6 and CYP3A4 on risperidone (active substance), in pill or injectable, does not affect the pharmacokinetics of the amount of aripiprazole and its active metabolite, dehydroatiprazole. Antiviral protease inhibitors: No data from official studies. However, since ritonavir is a strong CYP3A4 inhibitor and a weak CYP2D6 inhibitor, ritonavir and ritonavir-enhanced protease inhibitors may increase the concentration of active antipsychotic risperidone (active substance). Beta-blockers Ephototonary beta-blockers can increase the concentration in plasma of risperidone (active substance), but not active antipsychotic fraction. Verapamil calcium channel blockers, a moderate CYP3A4 inhibitor and P-gp inhibitor, increase the plasma concentration of risperidone (active substance) and active antipsychotic fraction. Digitalis glycosidesRsRperidone (active substance) does not demonstrate a clinically significant effect on dipoxin pharmacokinetics. Diureticsfurosamide: Increased mortality in elderly dementia patients who receive accompanying treatment with furosemid. Gastrointestinal receptor antagonists H2:Cimetidine and Ranitidine, both weak inhibitors CYP2D6 and CYP3A4, increased risperidone bioavailability but only marginally that of the active antipsychotic faction. Lithium-risperidone (active substance) does not show clinically relevant effects on the pharmacokinetic lithium. Tricyclic antidepressants and selective serotonin reuptake inhibitors Fluoxetine, a strong inhibitor of CYP2D6, increases the plasma concentration of Risperidone (active substance), but less than the active antipsychotic fraction. Paroxetine, a strong CYP2D6 inhibitor, increases the plasma concentration of Risperidone (active), but in doses up to 20 mg/day, less than the active antipsychotic fraction. However, higher doses of paroxetine may increase the concentration of the active antipsychotic fraction of risperidone (active substance). Tricyclic antidepressants may increase the concentration in Risperidone plasma (active substance) but not active antipsychotic fractions. Amitriptyline does not affect the pharmacokinetics of risperidone (active substance) or active antipsychotic fraction. Sertraline, mild INHIBITOR CYPD26 and fluvoxamine, weak CYP3A4, in doses up to 100 mg/day, are not associated with clinically significant changes in the active antipsychotic fraction of risperidone (active substance). However, doses of more than 100 mg/day of sertraline or fluvoxamine may increase the concentration of the active antipsychotic fraction of risperidone (active substance). Source: Risperdal Drug Professional Package Leaflet.Food Interaction Risperdal ConstaFoods do not affect the absorption of Risperidone (active substance). Risperidone (active substance) is metabolized mainly through CYPD26 and, to a lesser extent, through CYP3A4. Risperidone (active substance) and its active metabolite 9-hydroxy-risperidone (active substance) are substrates of glycoprotein-P (P-gp). Substances that alter the activity of CYP2D6 or substances that strongly induce the activity of CYP3A4 and/or glycoprotein-P may affect the pharmacokinetics of the antipsychotic fraction of risperidone (active substance). Source: Risperdal Drug Professional Bull.Risperdal Substance Action ConstaEfficacy ResultsSchizophreniaC evidence of short-term efficacy with oral risperidone (active substance) in the treatment of schizophrenia comes from 3 double-blind clinical studies, compared to active studies that involved a total of more than 2,200 patients with schizophrenia. Two of the three studies also had a placebo arm. The effectiveness of oral risperidone (active substance) in supporting schizophrenia treatment has been demonstrated in 2 double-blind studies, compared to active; 1 study lasting 12 months and 1 study lasting from 1 to 2 years. To ensure safety and efficiency with oral risperidone (active substance) in the mode of one daily dose, 3 double-blind studies were conducted. One of these three studies included a placebo hand. A total of 815 patients in these studies were treated with risperidone (active substance), of which 328 received a dose regimen of two daily doses and 487 daily dose doses. Both short- and long-term studies, as well as single-dose daily regimen studies, included adult patients diagnosed with schizophrenia in accordance with the criteria of the Diagnostic and Statistical Manual of Mental Disorders.An An open 12-week study was conducted to assess the safety and tolerance of oral risperidone (active substance) in older patients aged 65 years and older with SMD diagnosis of schizophrenia. The studies mentioned above used several tools to assess mental signs and symptoms, including positive and negative Scale Syndrome (PANSS), The Short Psychiatric Assessment Scale (BPRS), the Global Clinical Scale of Change Impressions (CGI-C) and (CGI-S), and the Negative Symptom Assessment Scale (SANS). Bipolar IA Disorder is evidence of the efficacy and safety of Risperidone (active substance) only in the treatment of bipolar I mania disorder based on the results of 3 randomized, double-blind, placebo-controlled studies. Two of these studies had a 3-week study and evaluated the efficacy and safety of Risperidone (active substance) compared to placebo. All patients who completed these studies were able to enter a 9-week study extending the open house. One study had a 3-week double-blind treatment period (Risperidone (active substance), haloperidol or placebo), followed by a 9-week maintenance period, as with double blind (Risperidone (active substance) or haloperidol (active substance) treatment. that consisted of a direct comparison of active weapons treatment (test product and active comparator) covering a period of 12 weeks. Patients in the placebo group who remained in the double-blind period after three weeks received Risperidone (active substance). Statistical 12-week comparisons included only those randomized patients for Risperidone (active substance) or haloperidol at the beginning of the study. Patients in the placebo group who switched to Risperidone (active substance) were not included in this Studies have been conducted to assess the efficacy and safety of Risperidone (active substance) in combination with mood stabilizers (lithium or valproate; and lithium, valproate and carbamazepine) compared to placebo in combination with mood stabilizers in the treatment of patients with bipolar disorder mania episodes. The study also included a haloperidol arm only as an internal reference to assessing the validity of the design and to facilitate the correct interpretation of the results of the studies. Both studies included a three-week two-blind phase followed by an open, uncontrolled phase of ten weeks. All clinical trials were conducted in patients with bipolar disorder I according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders of the 4th edition (DSM-IV). Studies of RIS-INT-69 and RIS-USA-239 included only patients with mania episodes. Studies of RIS-IND-2, RIS-USA-102 and RIS-INT-46 also included patients with mixed episodes, i.e. episodes of mania with concomitant symptoms of severe depression for at least seven days. In all clinical studies, Risperidone (active substance) was injected in a flexible dose range of 1 to 6 mg. Behavioral disorders in patients with dementia Risperidone (active substance) demonstrated their safety and effectiveness in treating one or more symptoms of behavioral and psychological dementia (BPSD) in three double-blind, placebo-controlled studies in older patients with dementia. A group analysis of the effectiveness of these studies presents data from 1,150 elderly patients admitted to the facility (722 treated with risperidone (active substance). Long-term safety data (up to 12 months) with risperidone (active substance) in elderly patients with dementia are also available. The population in each of these studies was patients who were hospitalized in a nursing home or hospital and presented behavioral disorders that had at least moderate problems for caregivers or dangerous to themselves. Studies included patients with a wide range of BPSD, based on the overall BEHAVE-AD score; The RIS-AUS-5 study specifically looked at patients who exhibited aggressive behavior based on a minimum rate of total aggression in the Cohen-Mansfield (CMAI) sub-school. Patients were recruited from the full spectrum of severity of dementia and cognitive impairment and Alzheimer's dementia, vascular dementia, or mixed diagnosis according to dsm-IV criteria. Patients with lewy-body dementia were excluded from RIS-AUS-5. Patients with other dementias or other neurological diseases that reduce cognitive function have been excluded from all patients with other psychological disorders. In Phase 3 of controlled studies, efficacy was evaluated using BEHAVE-AD and IMC to assess the severity and frequency of symptoms, respectively. The actuality of changes in the behavior scale was assessed using the CGI scale. Two more placebo-controlled, double-blind, were performed in a subgroup of patients with BPSD, in this case, patients with psychosis in Alzheimer's disease.Autism in children and adolescentsAcces the effectiveness of oral risperidone (active substance) in children and adolescents diagnosed with autism, as defined by the criteria of DSM-IV, was mainly based on two double-blind, placebo-controlled studies for which 8 weeks of the study. One study was a randomized, double-blind, parallel group, flexible dose, duration of 8 weeks, safety and efficacy of risperidone (active substance) in children and adolescents (ages 5 to 17 years and 2 months) with autism. The study was conducted by a network of pediatric psychopharmacological research units and sponsored by the National Institute of Mental Illness.Another study was a double-blind, randomized, parallel group, placebo-controlled, flexible dose, 8 weeks, safety and efficacy of Risperidone (active substance) in children between the ages of 5 and 12 years with autism or other TIDs. The main variable of efficacy in both studies was a baseline change in the final result in the subscribe of co-op or secondary efficacy in these studies. Studies have shown that Risperidone (active substance), in a modal average oral dose of 2.0 mg/day, significantly improves the symptoms of autism in children and adolescents between the ages of 5 and 17 years. The improvement was observed in the 2nd week and persisted at 4, 6 and 8 weeks. The results of the study showed that the modal average oral dose of 0.04 mg/kg/day of risperidone (active substance) significantly improves symptoms of autism or other TDs in children between the ages of 5 and 12 years. Clinically significant improvement with Risperidone (active substance) was observed in ABC subscales, corresponding symptoms of autism, including the underlying symptoms of impaired social interaction, communication disturbance, repetitive and stereotypical behaviors, interests and activities associated with symptoms of hyperactivity, lack of attention, aggressiveness towards others and with themselves, and anger scares. Efficiency was observed regardless of demographic subgroups (age/race/sex), presence/absence of drowsiness as an unfavorable event or intelligence factor. Oral Risperidone (active substance) was начальник ао плацебо пара reduce irritability ưлектронной significantly improved symptoms де Autism, конформные demonstrated by altera'es in the diferen'as of squares m'nimos да line де базы пара тодас как subscales ABC (irritability, lethargy ưлектронной reclus'o социальной, stereotyped behavior, hyperactivity ưлектронной inappropriate speech) e 3 subgroups де subscales ABC EM autism (irritability, lethargy ưлектронной reclus'o социальной, stereotyped behavior, hyperactivity). The results measured пела CGI-C confirm that как altera'es in ABC (measured by parents or caregiver) are clinically relevant and the percentage of patients who were responsive - CGI-C (much improvement the best a) was significant with Risperidone (active substance) - approximately 64.0% more and 32.4% (autism subgroup) patients were CGI-C responsive with Risperidone (active substance) than with placebo. Approximately 40.1% and 26.1% (autism subgroup) patients were ABC responsive with Risperidone (active substance) than with плацебо (decreases or improvement ≥ 50% да линха де база in at least 2 ABC subscales and no ABC demonstrated increase or worsening ≥ 10%). Борисон RL, Pathiraja AP, Diamond BI, Мейбах RC. Рисперидон: клиническая безопасность и ưффективность при шизофрении. Психофармакол Булл. 1992; 28(2):213.2. Chouinard G, Джонс B, Ремингтон G, Блум D, Аддингтон D, MacEwan GW, Labelle A, Боклер L, Арнотт B. Канадское многоцентровое плацеб контролируемое исследование фиксированных доз рисперидона и галоперидола в лечении хронических больных шизофренией. J Клин Психофармакол. 1993 февраль; 13(1):25-40. Ưрратум в: J Клин Психофармаколь 1993 Апр; 13(2):149.3. Мардер SR, Мейбах RC. Рисперидон в лечении шизофрении. Am J психиатрии 1994; 151(6): 825-835.4. Peuskens J. 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D, Aman MG, et al. (Research Units for Pediatric Psychopharmacology Autism Network): Double-blind, placebo-controlled risperidone trials in children with autism. N Engl J Med 2002; 347:314–321.15. Sarah Shea; Atilla Turgay, Alan Carroll, Miklos Schultz, Herbert Orlik, Isabel Smith and Fiona Dunbar. PEDIATRICS Vol. 114 No. 5 November 2004. Risperidone in the treatment of destructive behavioral symptoms in children with autism and other common developmental disorders.Fonte: Bula do Professional do Medicamento Risperdal.Caracter'sticas Farmacol'gicasPropriedades Farmacodin'micasMecanismo de a'oA Risperidona (substance) comprides. Ela tem uma alta afinidade pelos serotonin receptors 5-HT2 e dopamin'rgicos D2. Risperidone (substance ativa) liga-se igualmente aos receptors alpha-1 adren'rgicos e, com menor afinidade, aos receptors histamin'rgicos H1 e adren'rgicos alfa-2. Risperidone (substancia ativa) neo tem afinidade pelos receptor colinargicos. Apesar de Risperidone (Substance Ativa) ser um antagonist D2 potente, o que s considerado como a'o respons'vel pela melhora dos sintomas positivos da esquizofrenia, o seu efeito depressor da atividade motora e indutor de catalepsia s menos potente do que neuro os'pticos cl's. O antagonismo balancedo serotonin rgico e dopamin'rico central pode reduzir possibilidade de desenvolver efeitos extrapiramidais e estende atividade terap'tica sobre os sintomas negativos e afetivos da PharmacokineticsOral solution and tablets coated with risperidone (active substance) are bioevalent. Absorption of the risker (active substance) is completely absorbed after oral administration, reaching the peak of plasma concentration after 1-2 hours. Absorption does not change during feeding, and therefore Risperidone (active substance) can be swallowed during meals or not. Distribution of Risperidone (active substance) spreads rapidly. The distribution volume is 1-2 liters/kg. In plasma, risperidone (active substance) binds to albumin and alpha1 acid glycoprotein. The binding of risperidone (active substance) with plasma protein is 88% and 77% for 9-hydroxy-risperidone. A week after administration, 70% of the dose is excreted in the urine and 14% in the faeces. In urine, risperidone (active substance) plus 9-hydroxy-risperidone make up 35-45% dose. The rest are inactive metabolites. MetabolismRisperidone (active substance) is metabolized by CYP2D6 in 9-hydroxy-risperidone, which has a pharmacological activity similar to Risperidone (active substance). Thus, the active antipsychotic fraction is formed by risperidone (active substance) and 9-hydroxy-risperidone together. Another metabolic pathway of Risperidone (active substance) is N-desalkylation.EliminationAfter oral administration for psychotic patients, Risperidone (active substance) is eliminated from semi-life 3 hours. Elimination of the semi-oxygen 9-hydroxy-risperidone and active antipsychotic fraction is 24 hours. Dose proportionality Balance position is achieved in one day for Risperidone (active substance) and after 4-5 days for 9-hydroxy-risperidone in most patients. Concentrations in plasma of risperidone (active substance) are proportional to the dose in the therapeutic range. Special populationsPediatric patients: Pharmacokinetics Risperidone (active substance), 9-hydroxy-risperidone and active antipsychotic fraction in children are similar to those in adults. Renal and hepatic failure: A single-dose study showed higher active plasma concentrations and a decrease in plasma lumen of the active antipsychotic fraction of 30% in the elderly and 60% in patients with renal failure. Concentrations in plasma risperidone (active substance) were normal in patients with liver failure, but the average free share of risperidone (active substance) in plasma increased by about 35%. Preclinical dataIn (sub)chronic toxicity studies in which administration was initiated in sexually immature rats and dogs, dose-dependent effects were present in the sexual pathways of men and women and in the breast. These effects were related to increase in serum prolactin levels as a result of the activity of risperidone (active substance) blocking the dopaminergic receptor D2. In the study of toxicity for juvenile rats, there was an increase in the mortality of puppies and a delay in physical development. In a 40-week study in young dogs, sexual maturation was delayed in young dogs. Prolonged bone growth was not affected at a dose similar to the maximum dose for adolescents (6 mg/day). Effects were observed at a dose 4 times (based on AUC) or 7 times (based on mg/m2) maximum dose in adolescents. Source: Risperdal Medicine Professional Package Leaflet.Risperdal ConstaRisperdal Storage Care should be kept in the fridge (temperature 2 to 8 degrees Celsius). Protect from the light. This medicine is valid for 36 months from the date of manufacture. Number of packages and expiration dates: see do not use expired medicines. Keep it in the original packaging. The physical characteristics of Risperdal Const is white almost white powder. Off-the-match is a clear and colorless aqueous solution. With the right mixing, the suspension is homogeneous, thick and milky in color. Do not store the bottle after recovery, as the suspension will be deposited. Before use, watch the appearance of the medicine. If it is on its expiration date and you notice a change in appearance, consult your pharmacist to see if you can use it. All medicines must be kept within the reach of children. Risperdal ConstaMS Legal Statements - 1.1236.0031Farm. Resp.: Marcos R. Pereira-CRF/SP n' 12.304Regist:Janssen-Chilag Pharmacultica Ltd.Rua Gerivatiba, 207, Sao Paulo - SPCNPJ 51.780.468/0001-87Produary: Injectable Powder: Alkermes Inc., Wilmington, Ohio - USADiluent: CIlag, Hochstrasse, Schaffhausen - SwitzerlandPackage: Cilag AG, Hochstrasse, Schaffhausen - SwitzerlandImport:Janssen-Chilag Pharmacauticay Ltd.Rodia President Dutra, Km 154Sao Jose dos Camp -SPCNPJ 51.780.468/0002-68SAC 0800.7011851 on prescription. It can only be sold with withholding income. Editor's NoteData 2019-01-08Rating NameRating 5 5 risperdal consta bula pdf