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## Sprycel package insert pdf

Patient information leaflet (PIL) is a leaflet included in the package with the medicine. It is written for patients and provides information about the use or use of the medication. It is possible that the flyer in the drug packaging may be different from this version because it may have been updated since your medicine was packaged. Download the Flyer View Patient flyer in PDF format Below text only presentation of information about the patient flyer. The original flyer can be viewed here above. The text can only be accessed in large print, Braille, or audio CD. For more information call emc accessibility on 0800 198 5000. Product code (s) for this brochure: EU/1/06/363/008, EU/1/06/363/002, EU/1/06/363/011, EU/1/06/363/015, EU/1/06/363/001, EU/1/06/363/012, EU/1/06/363/014, EU/1/06/363/007, EU/1/06/363/005, EU/1/06/363/010, EU/1/06/363/013, EU/1/06/363/004. SPRYCEL 20 mg film-coated pill SPRYCEL 50 mg film-coated tablet SPRYCEL 70 mg film-coated tablet SPRYCEL 80 mg film-coated tablet SPRYCEL 100 mg film coated tablet SPRYCEL 140 mg film-coated dasatinib tablet Hold the leaflet. You may have to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine was prescribed only for you. Don't give it to others. This can harm them even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this brochure. See section 4. 1. What is SPRYCEL and what it is used for 2. What you need to know before taking SPRYCEL 3. How to take SPRYCEL 4. Possible side effects 5. How to store SPRYCEL 6. The contents of the packaging and other SPRYCEL information contain the active substance dasatinib. This medicine is used to treat chronic myeloid leukemia (HML) in adults, adolescents and children for at least 1 year. Leukemia is a cancer of white blood cells. These white cells usually help the body fight infection. In people with HML, white cells called granulocytes begin to grow out of control. SPRYCEL inhibits the growth of these leukemia cells. SPRYCEL is also used to treat Philadelphia chromosome positive (Ph) acute lymphoblastic leukemia (ALL) in adults, adolescents and children for at least 1 year, and lymphoid explosion of HML in adults who do not enjoy previous therapy. In humans with ALL, white cells called lymphocytes, they multiply too quickly and live too long. SPRYCEL inhibits the growth of these leukemia cells. If you have any questions about how SPRYCEL works or why this medication was prescribed to you, ask your doctor. If you are allergic to dasatinib or any of the other (listed in section 6). If you may be allergic, ask your doctor for advice. Talk to your doctor or pharmacist before using SPRYCEL if you are taking medication blood or prevent the formation of blood clots (see Other medications and SPRYCEL) if you have liver or heart problems, or used to have one if you start having difficulty breathing, chest pain, or cough when taking SPRYCEL: this may be a sign of fluid retention in the lungs or breasts (which may be more common in patients aged 65 years and older) , or due to changes in blood vessels Supplying your lungs if you have ever had or may now have a hepatitis B infection. Patients will be carefully checked by their doctor for signs of this infection prior to treatment. If you experience bruising, bleeding, fever, fatigue and confusion when taking SPRYCEL, see your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA). Your doctor will regularly monitor your condition to see if SPRYCEL has the desired effect. You will also have blood tests regularly while you take SPRYCEL. Don't give this medicine to children under one year old. There is limited experience with SPRYCEL in this age group. Bone growth and development will be carefully monitored in children taking SPRYCEL. Tell your doctor if you are taking, recently taken or may be taking any other medications. SPRYCEL is mostly treated by the liver. Some medications may interfere with SPRYCEL when working together. ketoconazole, itraconazole - is antifungal drugs erythromycin, claritromycin, telitromycin - this antibiotic ritonavir - is the antiviral medicine phenytoin, carbamazepine, phenobarbital - this patocy for epilepsy rifampicin - is a treatment of tuberculosis famotidin, Omeprazole is a medication that blocks St. John's wort gastric acid - an over-the-counter herbal drug used to treat depression and other conditions (also known as Hypericum perforatum) not to abut medications that neutralize gastric acids (antacids) 2 hours before or 2 hours after taking SPRYCEL. Tell your doctor if you are taking medication to thin your blood or prevent blood clots. Don't take SPRYCEL with grapefruit or grapefruit juice. If you are pregnant or think you may be pregnant, tell your doctor immediately. SPRYCEL should not be used during pregnancy if clearly necessary. Your doctor will discuss with you the potential risk of taking SPRYCEL during pregnancy. Both men and women taking SPRYCEL are advised to use effective contraception during treatment. If you are breastfeeding, tell your doctor. You should stop breastfeeding while you are taking SPRYCEL. Take care of the special driving or using cars in case you experience side effects such as dizziness and blurred vision. If you've been told your yours that you have intolerance to some sugars, talk to your doctor before taking this medicine. SPRYCEL will only be prescribed to you by a doctor with leukaemia treatment experience. Always take this medicine exactly as your doctor told you. See your doctor or pharmacist if you are unsure. SPRYCEL is designated for adults and children of at least 1 year. The starting dose recommended for adult patients with chronic phase 100 mg is 100 mg once a day. The starting dose recommended for adult patients with an accelerated or explosive crisis of HML or PHALL is 140 mg once a day. Dosing for children with chronic phase of HML or PHALL occurs on the basis of body weight. SPRYCEL is administered orally once a day in the form of either sprYCEL tablets or SPRYCEL powder for oral suspension. SPRYCEL tablets are not recommended for patients weighing less than 10 kg. Dose changes can occur when switching between formulations (i.e. tablets and oral suspension powder), so you should not switch from one to the other. Your doctor will decide the correct formulations and doses based on your weight, any side effects and response to treatment. The starting dose of SPRYCEL for children is calculated by body weight as shown below: Body weight (kg) daily dose (kg) from 10 to less than 20 kg 40 mg 20 to less than 30 kg 60 mg 30 to less than 45 kg 70 mg at least 45 kg 100 mg tablet is not recommended for patients weighing less than 10 kg. Oral suspension powder should be used for these patients. There is no recommendation for a dose of SPRYCEL for children under the age of 1. Depending on how you respond to treatment, your doctor may offer a higher or lower dose, or even stop treatment briefly. For higher or lower doses, you may need to take combinations of different strong pills. The tablets can come in packs with calendar blisters. These are blisters showing the days of the week. There are arrows to show the next pill that will be taken according to your treatment schedule. Take the pills at the same time every day. Swallow the tablets whole. Don't crush, cut or chew them. Don't take the scattered pills. You can't be sure that you will get the right dose if you crush, cut, chew or disperse the pill. SprYCEL tablets can be taken with or without food. SprYCEL tablets are unlikely to be broken. But if they do, individuals other than the patient should use gloves when handling SPRYCEL. Take SPRYCEL daily until your doctor tells you to stop. Make sure you take SPRYCEL as long as prescribed. If you accidentally take too many pills, talk to your doctor immediately. You medical attention is required. Don't take a double dose to get a forgotten pill. Take the next scheduled dose in regular time. If you have any further questions about the use of this medication, ask your doctor or pharmacist. Like all medications, this medication can cause side effects, although not everyone gets them. Below all this can be a sign of serious side effects: If you have chest pain, shortness of breath, cough and fainting, if you experience unexpected bleeding or bruising without injury, if you find blood in vomiting, stool or urine, or black stool, if you get signs of infections such as fever, severe chills, if you get fever, mouth pain or throat, blisters or peeling of your skin and/or Very common side effects (may affect more than 1 in 10 people) Infections (including bacterial, viral and fungal) Heart and lungs: shortness of breath digestive problems: diarrhea, feeling or being sick (nausea, vomiting) Skin, hair, eyes: common: skin rash, fever, swelling around the face, arm and swelling, headache Bleeding Pain: Muscle pain (during or after discontinuation of treatment), stomach (abdominal) pain Tests can show: low blood platelet levels, low white blood cell (neutropia), anemia, fluid around the lungs Common side effects (may affect up to 1 in 10 people) Infections: pneumonia, herpes virus infection (including cytomegalovirus - CMV), upper respiratory tract infections, serious blood or tissue infections (including rare fatalities) Heart and lungs : rapid heartbeat, irregular heartbeat, congestive heart failure, weak heart muscle, high blood pressure, high blood pressure in the lungs, problems with the digestive system: impaired taste, bloated or elongated tummy (abdominal), inflammation of the colon, constipation, heartburn, mouth ulcer, weight gain, weight loss, skin gastritis, hair, eyes, general permanent itnitus , hair loss, excessive sweating, visual disorder (including blurred vision and impaired vision), dry eyes, bruising, depression, insomnia, flushing, dizziness, bruise (injury), anorexia, doubt, generalized swelling pain: joint pain, muscle weakness, chest pain, pain around the arms and legs, chills, stiffness in the muscles and joints of the lungs, arrhythmia, febrile neutropenia, gastrointestinal bleeding, high levels of uric acid in the blood Unusual side effects (may affect up to 1 in 100 people) Heart and lungs: heart attack (including fatality), inflammation of the mucosa (fibrous surrounding heart, irregular heartbeat, chest pain due to lack of blood supply to the heart (angina), low blood pressure, narrowing of the airways, which can cause shortness of breath, asthma, high blood pressure arteries (blood vessels) of the lungs Digestive problems: inflammation of the pancreas, ulcers, inflammation of the food tube, swollen tummy (abdomene), rupture of the skin of the canal, difficulty swallowing, inflammation of the gallbladder, blockage of bile ducts, gastroesophageal reflux (a condition in which acid and other stomach contents return to the throat) : allergic reaction, including tender, red lumps on the skin (erythema nodosum), anxiety, anxiety, confusion, confusion, , inflammation of the eye, which causes redness or pain, skin diseases characterized by tender, red, clearly defined spots with sudden onset of fever and an increased number of white blood cells (neutrophilic dermatosis), hearing loss, visual impairment, skin color impairment, inflammation of the fatty tissue under the skin, skin ulcers, skin blisters, heart condition disorder, , menstrual disorder, general weakness and discomfort, low thyroid function, loss of balance when walking, osteonecrosis (disease of reduced blood flow to bones, which can lead to bone loss) , Arthritis, swelling in the skin anywhere in the body Pain: inflammation of the veins that can cause redness, tenderness and swelling, inflammation of the brain tendon: memory loss Tests may show: abnormal results of blood tests caused by the waste of a dying tumor (tumor lys syndrome), low levels of albumin in the blood, low levels of lymphocytes (a type of white blood cell) in the blood, high blood cholesterol, swollen lymph nodes, bleeding in the brain, irregularities in the electrical activity of the heart, enlarged heart, inflammation of the liver, protein in the urine, raised creatine phosphokinase (the enzyme is mainly found in the heart, brain and skeletal muscles), raised troponin (mainly found in the heart, brain and skeletal muscles) raised gamma-glutamyltransferase (ferment, mostly found in the liver) Rare side effects (may affect 1 in 1000 people) Heart lungs: expansion of the right ventricle in the heart, inflammation of the heart muscle, collection of states as a result of blockage of blood supply to the heart muscle (acute coronary syndrome), cardiac arrest (stopping blood flow from the heart), ischemic (heart) heart disease, inflammation of the tissues covering the heart and lungs, blood clots. : loss of vital nutrients such as protein from the digestive tract, bowel obstruction, fistula (abnormal opening from the anus to the skin around the anus), impaired kidney function, skin diabetes, hair, eyes, general: convulsions, inflammation nerve that can lead to complete or partial vision loss, blue-purple mottled skin, abnormally high thyroid function, thyroid inflammation, ataxia (a condition associated with lack of muscle coordination), difficulty walking, miscarriage, inflammation of the blood vessels of the skin, fibrosis of the skin of the brain: stroke, stroke, Temporary episode of neurological dysfunction caused by loss of blood flow, facial nerve paralysis, immune system dementia: severe allergic reaction of Muscoskeleta and connective tissue: joint delay slowing or delayed growth Of pneumonia bleeding in the stomach or intestines, which can lead to death Recurrence (reactivation) of hepatitis B infection when you had hepatitis B in past (liver infection) Reaction with fever, blisters on the skin, and ulcers of mucous membranes Kidney disease with symptoms including swelling and abnormal results of laboratory tests such as protein in the urine and low levels of protein in the blood blood vessel damage to blood vessels known as thrombotic microangiopathy (TMA) including reducing red blood cells, reducing platelets, and the formation of blood clots your doctor will check for some of these effects during treatment. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this brochure. You can also report side effects directly (see below for more details). By reporting side effects, you can help provide more information about the safety of this medication. Ireland HPRA Pharmacovigilance Malta ADR Report uk Yellow Card Scheme website: by www.mhra.gov.uk/yellowcard or search MHRA yellow card in Google Play or Apple App Store Keep this medicine out of sight and reach of children. Do not use this medicine after the expiration date, which is listed on the bottle label, blister or box after EXP. The expiration date refers to the last day of this month. This medicine does not require any special storage conditions. Do not throw away medicines through sewage or household waste. Ask your pharmacist how to throw away drugs you no longer use. These measures will help protect the environment. The active substance is dasatinib. Each tablet coated with film contains 20 mg, 50 mg, 70 mg, 80 mg, 100 mg or 140 mg of dasatinib (like monohydrate). Other ingredients are: tablet kernel: lactose monohydrate (see section 2 SPRYCEL contains lactose); microcrystal cellulose; sodium croscarmellose; hydroxypropylcellulose; magnesium stearat film-coating: hypromellose; Titanium dioxide (E171); macrogol 400 SPRYCEL 20 mg: a tablet coated with film white to white, biconvex, round with BMS debossed on one side and 527 on the other. SPRYCEL 50 mg: a tablet coated with film white up biconvex, oval with BMS debossed on one side and and On the other hand. SPRYCEL 70 mg: tablet coated film white to white, biconvex, round with BMS debossed on one side and 524 on the other. SPRYCEL 80 mg: tablet coated film white to white, biconvex, triangular with BMS 80 debossed on one side and 855 on the other. SPRYCEL 100 mg: tablet coated film white to white, biconvex, oval with BMS 100 debossed on one side and 852 on the other. SPRYCEL 140 mg: tablet coated film white to white, biconvex, round with BMS 140 debossed on one side and 857 on the other. SPRYCEL 20 mg, 50 mg or 70 mg tablets with coating film are available in boxes containing 56 film-coated tablets in 4 calendar blisters 14 film-coated tablets each, and in boxes containing 60 x 1 film tablets in perforated unit doses of blisters. They are also available in children's closure bottles containing 60 tablets coated with film. Each box contains one bottle. SPRYCEL 80 mg, 100 mg or 140 mg tablets with coating film are available in boxes containing 30 x 1 tablets coated with film in a perforated unit dose of blisters. They are also available in children's closure bottles containing 30 tablets coated with film. Each box contains one bottle. Not all packaging sizes can be on the market. Bristol-Myers Squibb Pharma EEIGPlaza 254Blanchardstown Corporate Park 2Dublin 15D15 T867Ireland Swords Lab T/A Bristol-Myers Squibb Pharmaceutical Operations, External ManufacturingPlaza 254Blanchardstown Corporate Park 2Dublin 15D15 T867Ireland CATALENT ANA S.R.L.L. Fontana del Ceraso sncStrada Provinciale 12 Casilina, 4103012 Anagni (FR) Italy For any information about this medication, please contact your local marketing representative Authorizing Holder: Bristol-Myers Squibb Pharmaceuticals Ltd This brochure was last revised in April 2020 Details of this drug available on the European Medicines Agency website: . There are also links to other websites about rare diseases and treatments. Procedures. sprycel package insert pdf

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