Dasatinib SPRYCEL[®] and generics

Patient information sheet V3, April 2024



WHAT IS SPRYCEL® DASATINIB?

- A targeted therapy used to treat some forms of blood cancer (leukaemia).
- Prescribed and renewed by your hospital-based oncologist, cancer specialist or haematologist.
- Available from community pharmacies on presentation of your prescription.

White to off-white film-coated tablet with five available doses:
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- 20 mg: with "BMS" on one side and "527" on the other
 - **50 mg:** with "BMS" on one side and "528" on the other
- 70 mg: with "BMS" on one side and "524" on the other
- 100 mg: with "BMS 100" on one side and "852" on the other
- **140 mg:** with "BMS 140" on one side and "857" on the other Generic medicines may have a different form or colour
- Store at room temperature, and keep out of the sight and reach of children.
- Do not take the tablets out of the box to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- Do not throw away opened boxes, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?	= 1 dose per day, with or without a meal	
How?	C T	Swallow the tablets whole, with water, one after another, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **medical diary**^{*} and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor. This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- **If you forget to take your medicine**, do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.
- **If you throw up**, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit** and **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.



- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment.
- Stop breastfeeding during treatment.

* Patient diary available (in French) at <u>www.omedit-fiches-cancer.fr</u>

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WHAT SIDE EFFECTS CAN OCCUR WITH SPRYCEL® DASATINIB?

9	Side effects	Prevention			
2	Risk of infection	Limit contact with people with infections. Wash your hands regularly. Disinfect all wounds thoroughly. Contact your doctor in case of temperature > 38°C, cough, shortness of breath/pain on breathing, pain when urinating/smelly urine, change in type/frequency of bowel movements (diarrhoea, constipation), or in case of redness, pain or discharge around your central line, feeding tube or urinary catheter.			
P	Low red blood cells, white blood cells and platelets	Low red blood cells: contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches. Low white blood cells: contact your doctor in case of temperature > 38°C, chills, sweating, cough, shortness of breath/pain when breathing, a burning sensation when urinating, diarrhoea accompanied by fever or any other signs suggesting infection. Low platelets: contact your doctor in case of small red dots on your skin, bruising, nosebleeds, bleeding eyes or gums, or blood in your urine or faeces.			
	Digestive effects: diarrhoea, abdominal pain, nausea, vomiting	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of diarrhoea, eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). In case of nausea/vomiting, divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.			
45	Headache	Remember to hydrate! Eat at regular intervals, do not skip meals. Avoid tobacco and alcohol (headache triggers). Avoid going to bed and getting up late; get sufficient sleep at night.			
•	Unusual bleeding, bruising	Use a soft toothbrush. Do not use rectal thermometers. Do not take aspirin, anti- inflammatories (e.g. Ibuprofen), or herbal products (that can increase bleeding) without medical guidance: consult a healthcare professional. In case of bruising, apply cold (compress or ice pack) or a suitable cream/gel (e.g. arnica) if the skin is not broken.			
t	Swelling of the face or limbs	Eat a diet low in salt. Avoid tight clothing. If your legs swell, raise your feet when sitting. Wear compression stockings; put them on when getting up in the morning. Weigh yourself regularly. Consult your doctor if this type of swelling occurs.			
-``do`-	Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine of your dector or pharmaciet				

Like all medicines, dasatinib may cause side effects, although not everybody gets them.

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Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.

You can also ask your <u>Regional Pharmacovigilance Centre</u> and report any side effects online: <u>signalement-sante-gouv-fr</u>

Remember

Remember to go for the lab tests prescribed by your doctor.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Contact your doctor rapidly in case of:

- Signs of infection (fever, cough, chills, burning sensation when urinating, etc.)
- Chest pain, difficulty breathing, cough
- Unusual bleeding, bruising, bloody urine
- Any persistent or worsening side effect



Useful contacts:

Note: