Dasatinib SPRYCEL[®] liquid

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 hospital pharmacies on presentation of your prescription.
 - Opaque white to yellow oral suspension, dosed at 10 mg/mL
 - Your pharmacist or qualified healthcare professional will constitute (mix to form a liquid) the oral suspension before dispensing to you.
 - Bottle supplied with 12 mL syringe for oral administration
 - Store in a refrigerator (2°C 8°C) for up to 60 days.

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- Keep the bottle upright, and keep out of the sight and reach of children.
- Wash your hands carefully before and after handling the suspension.
- Do not throw away opened bottles, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

= 1 dose per day, with or without a meal Can be mixed with milk, yoghurt, apple juice or applesauce.

When?

(1) Shake the bottle (~ 30 seconds), remove the lid and check the adapter is firmly pressed into the bottle. (2) Make sure the plunger on the 12 mL syringe provided is pushed to the bottom of the barrel, then, with the bottle in an upright position, firmly insert the tip of the syringe into the adapter. (3) Keeping the syringe tip firmly in the bottle, turn the bottle so the syringe points downwards. (4) Withdraw the correct

amount by slowly pulling the syringe plunger. ③ Keeping the syringe tip firmly in the bottle turn the bottle again. ⑥ Remove the syringe from the bottle. ⑦ Place the syringe in the mouth, between the side of the mouth and the tongue, then slowly push the plunger down until all of the dose has been given. If more than 11 mL is to be given, repeat steps 2 to 7. ⑧ Wash the syringe with water after each use, without taking it apart. Do not wash in a dishwasher.

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?

2	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.
Ť	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.
-`@`-	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.	

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

your doctor or pharmacist.

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

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: