

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What Absoban® is and what it is used for
2. What you need to know before you are given Absoban®
3. How Absoban® is used
4. Possible side effects
5. How to store Absoban®
6. Contents of the pack and other information



1. What Absoban® is and what it is used for

Abemaciclib (the active substance of Absoban®) is a selective inhibitor of cyclin-dependent kinases 4 and 6, which leads to disruption of cancer cell proliferation. Absoban® is used for the treatment of locally advanced or certain types of metastatic breast cancer (hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-).



2. What you need to know before you are given Absoban®

Do not take Absoban®:

- if you are allergic to Abemaciclib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Absoban® may:

- Reduce the number of your white blood cells, and you may be at greater risk of getting an infection. Serious infections such as lung infections can be life-threatening.
 - Cause blood clots in the veins.
 - Cause severe or life-threatening inflammation of the lungs.
 - Affect the way your liver works.
 - Cause diarrhea. At the first sign of diarrhea, start treatment with antidiarrhoeal agents, such as loperamide. Drink plenty of fluids.
 - Cause blood clots in the arteries in patients also receiving hormone therapies.
- See section 4 "Possible side effects", and talk to your doctor if you have any symptoms.

What your doctor will check before and during your treatment

You will have regular blood tests before and during treatment to check whether Absoban® affects your blood (white blood cells, red blood cells, platelets) or the concentration of liver enzymes in your blood.

Children and adolescents

Absoban® is not to be used in children and adolescents under 18 years of age.

Other medicines and Absoban®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist before taking Absoban® if you are taking the following:

- Medicines that may increase the concentration of Absoban® in the blood:

- Clarithromycin (antibiotic used to treat bacterial infections)
- Itraconazole, ketoconazole, posaconazole, voriconazole (used to treat fungal infections)
- Lopinavir/ritonavir (used to treat HIV/AIDS)
- Digoxin (used to treat heart disorders)
- Dabigatran etexilate (used to reduce the risk of stroke and blood clots)

- Medicines that may reduce the effectiveness of Absoban®:

- Carbamazepine (anti-epileptic used to treat seizures or fits)
- Rifampicin, used to treat tuberculosis (TB)

- Phenytoin (used to treat seizures)
- St. John's wort (a herbal product used to treat mild depression and anxiety)

Absoban® with food and drink

Avoid grapefruit or grapefruit juice while you are taking the medicine as they may increase the concentration of Absoban® in the blood.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not use Absoban® if you are pregnant.

You should avoid becoming pregnant while taking Absoban®.

If you are able to have children, you should use adequate contraceptive methods (e.g., double -barrier contraception such as condom and diaphragm) during therapy and for at least 3 weeks after completing therapy. Discuss contraception with your doctor if there is any possibility that you may become pregnant.

You must tell your doctor if you become pregnant.

Breast-feeding

You should not breast-feed while taking Absoban®. It is not known if Absoban® passes into breast milk.

Fertility

Absoban® may decrease fertility in men. Talk to your doctor to seek advice about fertility prior to treatment.

Driving and using machines

Tiredness and dizziness are very common side effects. If you feel unusually tired or dizzy, take special care when driving or using machines.

Hepatic impairment

Use with caution in severe impairment. Temporary or permanent withdrawal may be needed following increases in aminotransferases.

Dose adjustments: Dose reduction to 150 mg once daily in severe impairment.

Renal impairment

Use with caution in severe impairment—monitor for signs of toxicity.

Monitoring requirements

Monitor full blood count, and alanine and aspartate aminotransferases before starting treatment, every 2 weeks for the first 2 months, monthly for the following 2 months, and as clinically indicated thereafter.

Patient and carer advice

Patients should be instructed to start an antidiarrhoeal such as loperamide, increase oral fluids, and seek medical advice at the first sign of loose stools. Patients should also be instructed to seek medical advice if fever occurs.



3. How Absoban® is used

Recommended dose

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When given together with endocrine therapy to treat your breast cancer, the recommended dose of Absoban® is 150 mg taken by mouth twice daily.

If you get certain side effects while you are taking Absoban®, your doctor may lower your dose or stop treatment temporarily or permanently.

When and how to take Absoban®

Take Absoban® twice daily, at about the same time every day, preferably in the morning and evening.

You can take the tablets either with or without food, just avoid grapefruit and grapefruit juice (see section 2 "Absoban® with food and drink").

Swallow the tablet whole with a glass of water.

Do not chew, crush or split the tablets before swallowing.

How long to take Absoban®

Take Absoban® continuously for as long as your doctor tells you to.

If you take Absoban® for early breast cancer treatment, you should take it for up to 2 years.

If you take more Absoban® than you should

If you take too many tablets, or if someone else takes your medicine, contact a doctor or hospital for advice. Show the Absoban® box and this leaflet. Medical treatment may

be necessary.

If you miss a dose of Absoban®

If you vomit after taking the dose or forget a dose, take your next dose at your usual time. Do not take a double dose to make up for the forgotten or vomited dose.

If you stop taking Absoban®

Do not stop taking Absoban® unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.



4. Possible side effects

Common or very common

Alopecia, anemia, decreased appetite, decreased leucocytes, diarrhea, dizziness, embolism and thrombosis, excessive tearing, fatigue, fever, infection, muscle weakness, nausea, neutropenia, respiratory disorders, skin reactions, taste altered, thrombocytopenia, vomiting, inflammation or sore mouth, headache, itching, rash, abnormalities in liver blood tests, dry skin, inflammation of the lungs which causes breathlessness, cough and raised temperature, indigestion or upset stomach, nail disorders such as breaking or splitting of nails

Uncommon

Low levels of white blood cells with fever, perception of flashes of light or floaters in your vision

Rare

A skin reaction that causes red spots or patches on the skin that may be a dark red center surrounded by paler red rings (erythema multiforme).



5. How to store Absoban®

- Store below 30°C and protect from moisture.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box after "EXP". The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.



6. Contents of the pack and other information

What Absoban® contains

- The active substance is Abemaciclib.

Absoban® film-coated tablets come in different strengths:

- Absoban® 50 mg film-coated tablet: Each tablet contains 50 mg Abemaciclib.
- Absoban® 100 mg film-coated tablet: Each tablet contains 100 mg Abemaciclib.
- Absoban® 150 mg film-coated tablet: Each tablet contains 150 mg Abemaciclib.
- Absoban® 200 mg film-coated tablet: Each tablet contains 200 mg Abemaciclib.

- The other ingredients are:

microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, colloidal silicon dioxide, sodium stearyl fumarate

What Absoban® looks like and contents of the pack

Absoban® 50 mg, 100mg, 150mg and 200mg tablets are yellow colored, film-coated tablets.

Each box contains 28 film-coated tablets (4 blisters of 7 tablets).

 Sobhan Oncology Co.

Leaflet	Absoban
Color	PANTONE 295 U 
Size	210 mm x 297 mm Tolerance: 1±mm
Grammage	58-72 g/m²
File Name	ACBT-0000-LF-00
date	03.06.05