

Imatinib NEAPOLIS

Imatinib 100mg - 400mg

Imatinib mesilate
Film-coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What is IMATINIB NEAPOLIS and in which case is it used?
2. What you need to know before you take IMATINIB NEAPOLIS?
3. How to take IMATINIB NEAPOLIS?
4. Possible side effects
5. How to store IMATINIB NEAPOLIS?
6. Content of the packaging and other information

1. What is IMATINIB NEAPOLIS and in which case is it used?

IMATINIB NEAPOLIS is a medicine containing an active substance called imatinib. This medicine works by inhibiting the growth of abnormal cells in the diseases listed below. These include some types of cancer.

IMATINIB NEAPOLIS is indicated for treatment in:

- adult and pediatric patients with Ph+ chronic myeloid leukaemia (Ph+ CML) in accelerated phase and blast crisis
- adult and pediatric patients with Ph+ acute lymphoid leukemia (Ph+ ALL) in combination with standard chemotherapy
- adult patients with hypereosinophilic syndrome (HSE), atypical myelodysplastic / myeloproliferative disease (MDS / MPD), or aggressive subtype of systemic mastocytosis (SM) associated with eosinophilia and / or platelet-derived growth factor (PDGF) alpha or beta, or to a fusion protein FP1L1-PDGFR-alpha
- unresectable and / or metastatic malignant gastrointestinal stromal tumors (GIST) in adults
- adjuvant in adults with significant risk of recurrence after resection of GIST c-Kit (CD 117) positive: patients with low risk of recurrence should not receive adjuvant therapy
- adults with unresectable, recurrent or metastatic dermatofibrosarcoma protuberant (DFSP)

In the rest of this leaflet, we will use the abbreviations when talking about these diseases.

If you have any questions about how IMATINIB NEAPOLIS works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take IMATINIB NEAPOLIS?

IMATINIB NEAPOLIS will only be prescribed to you by a doctor with experience in medicines to treat blood cancers or solid tumours.

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Do not take IMATINIB NEAPOLIS:

- if you are allergic to imatinib or any of the other components of this medicine (listed in section 6).
- If this applies to you, **tell your doctor without taking IMATINIB NEAPOLIS.**

If you think you may be allergic but are not sure, ask your doctor for advice.

Warnings and precautions

Talk to your doctor before taking IMATINIB NEAPOLIS:

- if you have or have ever had a liver, kidney or heart problem.
- if you are taking the medicine levothyroxine because your thyroid has been removed.
- if you have ever had or might now have a hepatitis B infection. This is because imatinib could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.

If any of these apply to you, **tell your doctor before taking IMATINIB NEAPOLIS.**

During treatment with imatinib, tell your doctor immediately if you put on weight very quickly. Imatinib may cause your body to retain water (severe fluid retention).

While you are taking **IMATINIB NEAPOLIS**, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

Children and adolescents

IMATINIB NEAPOLIS is also a treatment for children with CML. There is no experience with imatinib in children with CML below 2 years of age. There is limited experience in children with Ph-positive ALL and very limited experience in children with MDS/MPD, DFSP, GIST and HES/CEL.

Some children and adolescents taking imatinib may have slower than normal growth. The doctor will monitor the growth at regular visits.

Other medicines and IMATINIB NEAPOLIS

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (such as paracetamol) and including herbal medicines (such as St. John's Wort). Some medicines can interfere with the effect of IMATINIB NEAPOLIS when taken together. They may

increase or decrease the effect of IMATINIB NEAPOLIS, either leading to increased side effects or making IMATINIB NEAPOLIS less effective. IMATINIB NEAPOLIS may do the same to some other medicines. Tell your doctor if you are using medicines that prevent the formation of blood clots.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning pregnancy, ask your doctor for advice before taking this medicine.
- Imatinib is not recommended during pregnancy unless clearly necessary as it may harm your baby. Your doctor will discuss with you the possible risks of taking Imatinib during pregnancy.
- Women who might become pregnant are advised to use effective contraception during treatment.
- Do not breastfeed during the treatment with imatinib.
- Patients who are concerned about their fertility while taking imatinib are advised to consult with their doctor.

Driving and using machines

You may feel dizzy or drowsy or get blurred vision while taking this medicine. If this happens, do not drive or use any tools or machines until you are feeling well again.

3. How to take IMATINIB NEAPOLIS?

Your doctor has prescribed IMATINIB NEAPOLIS because you suffer from a serious condition. IMATINIB NEAPOLIS can help you to fight this condition.

However, always take this medicine exactly as your doctor or pharmacist has told you. It is important that you do this as long as your doctor or pharmacist tells you to. Check with your doctor or pharmacist if you are not sure.

Do not stop taking IMATINIB NEAPOLIS unless your doctor tells you to. If you are not able to take the medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor immediately.

How much IMATINIB NEAPOLIS to take

Use in adults

Your doctor will tell you exactly how many tablets of IMATINIB NEAPOLIS to take.

- If you are being treated for CML:

Depending on your condition the usual starting dose is either 400 mg or 600 mg:

- **400 mg** to be taken as 4 tablets of Imatinib 100mg **once** a day or as one tablet of Imatinib 400mg **once** a day,
- **600 mg** to be taken as 6 tablets of Imatinib 100mg **once** a day or to be taken as one tablet of 400 mg plus 2 tablets of 100 mg **once** a day.

- If you are being treated for GIST:

The starting dose is 400 mg, to be taken as 4 tablets of 100mg **once** a day or as one tablet of 400mg **once** a day.

For CML and GIST, your doctor may prescribe a higher or lower dose depending on how you respond to the treatment. If your daily dose is 800 mg (8 tablets of Imatinib 100mg), you should take 4 tablets in the morning and 4 tablets in the evening or (2 tablets of Imatinib 400mg), you should take one tablet in the morning and a second tablet in the evening.

- If you are being treated for Ph+ ALL:

The starting dose is 600 mg to be taken as 6 tablets of 100mg **once** a day or to be taken as one tablet of 400 mg plus 2 tablets of 100 mg **once** a day.

- If you are being treated for MDS/MPD:

The starting dose is 400 mg to be taken as 4 tablets of 100mg **once** a day or as one tablet of 400mg **once** a day.

- If you are being treated for HES:

The starting dose is 100 mg, to be taken as one tablet **once** a day. Your doctor may decide to increase the dose to 400 mg, to be taken as 4 tablets of 100mg **once** a day or as one tablet of 400 mg **once** a day, depending on how you respond to the treatment.

- If you are being treated for DFSP:

The dose is 800 mg per day (8 tablets of Imatinib 100mg), to be taken as 4 tablets in the morning and 4 tablets in the evening or (2 tablets of Imatinib 400mg), to be taken as one tablet in the morning and a second tablet in the evening.

Use in children and adolescents

The doctor will tell you how many tablets of IMATINIB NEAPOLIS to give to your child. The amount of IMATINIB NEAPOLIS given will depend on your child's condition, body weight and height. The total daily dose in children must not exceed 800 mg with CML and 600 mg with Ph+ ALL. The treatment can either be given to your child as a once-daily dose or alternatively the daily dose can be split into two administrations (half in the morning and half in the evening).

When and how to take IMATINIB NEAPOLIS

- **Take IMATINIB NEAPOLIS with a meal.** This will help protect you from stomach problems when taking IMATINIB NEAPOLIS.
- **Swallow the tablets whole with a large glass of water.**

If you are unable to swallow the tablets, you can dissolve them in a glass of flat water or apple juice:

- Use about 50 ml for each 100 mg tablet or about 200 ml for each 400 mg tablet
- Stir with a spoon until the tablets have completely dissolved.
- Once the tablet has dissolved, drink everything in the glass immediately. Traces of the dissolved tablets may be left behind in the glass.

How long to take IMATINIB NEAPOLIS?

Keep taking IMATINIB NEAPOLIS every day for as long as your doctor tells you.

Imatinib NEAPOLIS

Imatinib 100mg - 400mg

Imatinib mesilate
Film-coated tablets

If you take more IMATINIB NEAPOLIS than you should

If you have accidentally taken too many tablets, talk to your doctor **immediately**. You may require medical attention. Take the medicine pack with you.

If you forget to take IMATINIB NEAPOLIS

- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Then continue with your normal schedule.
- Do not take a double dose to make up for the dose you forgot to take.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. They are usually mild to moderate.

Some side effects may be serious. Tell your doctor immediately if you get any of the following:

Very common (may affect more than 1 in 10 people) **or common** (may affect up to 1 in 10 people):

- Rapid weight gain. Imatinib may cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Imatinib can reduce the number of white blood cells, so you might get infections more easily.
- Unexpected bleeding or bruising (when you have not hurt yourself).

Uncommon (may affect up to 1 in 100 people) **or rare** (may affect up to 1 in 1,000 people):

- Chest pain, irregular heart rhythm (signs of heart problems).
- Cough, having difficulty breathing or painful breathing (signs of lung problems).
- Feeling light-headed, dizzy or fainting (signs of low blood pressure).
- Feeling sick (nausea), with loss of appetite, dark-colored urine, yellow skin or eyes (signs of liver problems).
- Rash, red skin with blisters on the lips, eyes, skin or mouth, peeling skin, fever, raised red or purple skin patches, itching, burning sensation, pustular eruption (signs of skin problems).
- Severe abdominal pain, blood in your vomit, stools or urine, black stools (signs of gastrointestinal disorders).
- Severely decreased urine output, feeling thirsty (signs of kidney problems).
- Feeling sick (nausea) with diarrhea and vomiting, abdominal pain or fever (signs of bowel problems).
- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system problems such as bleeding or swelling in skull/brain).
- Pale skin, feeling tired and breathlessness and having dark urine (signs of low levels of red blood cells).
- Eye pain or deterioration in vision, bleeding in the eyes.
- Pain in your hips or difficulty walking.
- Numb or cold toes and fingers (signs of Raynaud's syndrome).
- Sudden swelling and redness of the skin (signs of a skin infection called cellulitis).
- Difficulty hearing.
- Muscle weakness and spasms with an abnormal heart rhythm (signs of changes in the amount of potassium in your blood).
- Bruising.
- Stomach pain with feeling sick (nausea).
- Muscle spasms with a fever, red-brown urine, pain or weakness in your muscles (signs of muscle problems).
- Pelvic pain sometimes with nausea and vomiting, with unexpected vaginal bleeding, feeling dizzy or fainting due to low blood pressure (signs of problems with your ovaries or womb).
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory test results (eg. high potassium, uric acid and calcium levels and low phosphorous levels in the blood).

Not known (frequency cannot be estimated from the available data):

- Combination of a widespread severe rash, feeling sick, fever, high level of certain white blood cells or yellow skin or eyes (signs of jaundice) with breathlessness, chest pain/discomfort, severely decreased urine output and feeling thirsty etc. (signs of a treatment-related allergic reaction).
- Chronic renal failure.
- Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection).

If you get any of the above, **tell your doctor immediately.**

Other side effects may include:

Very common (may affect more than 1 in 10 people):

- Headache or feeling tired.
- Feeling sick (nausea), being sick (vomiting), diarrhea or indigestion.
- Rash.
- Muscle or joint cramps, muscle or bone pain, during imatinib treatment or after you have stopped taking imatinib.
- Swelling such as round your ankles or puffy eyes.
- Weight gain.

If any of these affects you severely, **tell your doctor.**

Common (may affect up to 1 in 10 people):

- Anorexia, weight loss or a disturbed sense of taste.
- Feeling dizzy or weak.
- Difficulty in sleeping (insomnia).
- Discharge from the eye with itching, redness and swelling (conjunctivitis), watery eyes or having blurred vision.
- Nose bleeds.
- Pain or swelling in your abdomen, flatulence, heartburn or constipation.
- Itching.
- Unusual hair loss or thinning.
- Numbness of the hands or feet.

- Mouth ulcers.
- Joint pain with swelling.
- Dry mouth, dry skin or dry eye.
- Decreased or increased skin sensitivity.
- Hot flushes, chills or night sweats.

If any of these affects you severely, **tell your doctor.**

Not known (frequency cannot be estimated from the available data):

- Reddening and/or swelling on the palms of the hands and soles of the feet which may be accompanied by tingling sensation and burning pain.
- Slowing of growth in children and adolescents.

If any of these affects you severely, **tell your doctor.**

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store IMATINIB NEAPOLIS?

- 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 carton.
- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- Do not use any pack that 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. Content of the packaging and other information

What IMATINIB NEAPOLIS contains

- The active substance is imatinib mesilate. Each tablet of IMATINIB NEAPOLIS contains 100 mg imatinib (as mesilate). And each tablet of IMATINIB NEAPOLIS contains 400 mg imatinib (as mesilate).
- The other components are microcrystalline cellulose, crospovidone, hypromellose, magnesium stearate and anhydrous colloidal silica.
- The tablet coating is made of red iron oxide, yellow iron oxide, talc, titanium dioxide, macrogol/polyethylene glycol and polyvinyl alcohol.

What does IMATINIB NEAPOLIS look like and content of the packaging

IMATINIB NEAPOLIS 100 mg film-coated tablets are very dark yellow to brownish-orange round tablets. They have "N19" on one side and a score line on the other side. They are supplied in packs containing 30 or 60 tablets.

IMATINIB NEAPOLIS 400 mg film-coated tablets are very dark yellow to brownish-orange ovaloid biconvex tablets. They have "N20" on one side. They are supplied in packs containing 30 tablets

Prescription and supply conditions: list I

M.A. N°:

IMATINIB NEAPOLIS 100mg, box of 30 film-coated tablets: 9393141H

IMATINIB NEAPOLIS 100mg, box of 60 film-coated tablets: 9393142H

IMATINIB NEAPOLIS 400mg, box of 30 film-coated tablets: 9393143H

Marketing Authorization Holder and manufacturer

Neapolis Pharma

Road of Tunis Km 7 PB 206 Nabeul 8000 - Tunisia.
Tel: +216.31.338.400 / FAX: +216.72.235.016/ +216.31.338.421
E.mail: neapolispharma@neapolispharma.com

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THIS IS A MEDICINE

- A medicine is a product but not like the others.
- A medicine is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.
- Your doctor and pharmacist are familiar with the medicine, its indications and contraindications.
- Do not stop treatment on your own initiative during the prescribed period.
- Do not take it again, do not increase the doses without consulting your doctor.

KEEP THE MEDICINES OUT OF THE REACH OF CHILDREN

