

IMATINIB APOTEX

Contains the active ingredient imatinib mesilate

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some of the common questions about imatinib. It does not contain all the information that is known about this medicine.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

The name of your medicine is IMATINIB APOTEX. It contains the active ingredient imatinib mesilate.

Imatinib is used to treat adults and children/adolescents who have chronic myeloid leukaemia (CML) and acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL).

CML and ALL are types of leukaemia in which an abnormal chromosome produces an enzyme that leads to uncontrolled growth of white blood cells. Imatinib kills the abnormal cells while leaving normal cells alone.

Imatinib is also used to treat adults for:

- **myelodysplastic / myeloproliferative diseases (MDS/MPD).**
These are a group of blood diseases in which some blood cells start growing out of control.
- **Aggressive systemic mastocytosis (ASM).**
It is a cancer in which certain blood cells, called "mast" cells, grow out of control.
- **Hyper eosinophilic syndrome (HES) and or chronic eosinophilic leukaemia (CEL).**
These are blood diseases in which some blood cells, named "eosinophils", start growing out of control.
- **Dermatofibrosarcoma protuberans (DFSP).**
DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control.

Imatinib works by slowing the growth of abnormal cells. Imatinib kills the abnormal cells while leaving normal cells alone.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor, however, may prescribe it for another purpose.

Imatinib is only available with a doctor's prescription. It is not addictive.

Use in children

There is not enough information to recommend the use of imatinib in children under 3 years of age for most uses. For use in CML, there is no experience with the use of imatinib in children below 2 years of age. For acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-

positive ALL), there is no experience with the use of imatinib in children below 1 year of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you have ever had an allergic reaction to imatinib (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return the medicine to your pharmacist.

Before you start to take it

Tell your doctor if you are pregnant or intend to become pregnant.

This medicine may be harmful to your unborn baby. If it is necessary for you to take it during pregnancy, your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is not known whether imatinib passes into breast milk. Because this medicine could affect your baby, breastfeeding is not recommended.

Tell your doctor if you have ever had any of the following medical problems or procedures:

- kidney or liver problems
- problems with your heart
- you have had your thyroid gland removed.

Your doctor may want to take special precautions in that case.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and imatinib may interfere with each other. These include many medicines that are eliminated from the body through the liver:

- St. John's wort, a herbal medicine found in many products that you can buy without a prescription
- paracetamol, a medicine found in many common pain relievers and cold remedies (e.g. Panadol®, Panadeine®, Codral®, Tylenol®) which are known to be associated with liver toxicity.
- A patient, who was taking paracetamol regularly for fever, died of acute liver failure. Although the cause is currently unknown, special caution should be exercised when using paracetamol and imatinib.
- antibiotic medicines such as rifampicin, ketoconazole, erythromycin, clarithromycin, itraconazole

- antiviral medicines used to treat HIV/AIDS
- dexamethasone, a steroid medicine
- medicines for high cholesterol, such as simvastatin
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone
- warfarin, a medicine used to prevent blood clots
- some medicines used to treat mental disorders and depression
- some medicines used to treat high blood pressure and heart problems
- cyclosporin

You may need to take different amounts of these medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start taking this medicine

How to take this medicine

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

For CML, the usual dose for an adult is 400 to 600 mg each day and the maximum dose is 800 mg each day. The dose depends on what stage of CML you have. For Ph-positive ALL the usual dose is 600 mg each day. For children treated with CML and Ph-positive ALL, the dose depends on the size of the child.

For MDS/MPD, the starting dose is 400 mg.

For ASM and HES/CEL, the usual starting dose is 400 mg. For some patients the starting dose may be 100 mg.

For DFSP, the starting dose is 800 mg per day.

Daily dose of 400 mg should be taken as one capsule of 400 mg once a day.

Daily dose of 600 mg should be taken as either:

- six capsules of 100 mg or
- one capsule of 400 mg plus two capsules of 100 mg once a day.

Daily dose of 800 mg should be taken as 400 mg twice a day, in the morning and in the evening.

Your doctor may direct you to take a higher or lower dose, depending on your response to imatinib.

Imatinib is usually taken as a single dose each day. However, your doctor may want you to take them in two doses, one in the morning and one in the evening.

How to take it

Take the medicine with a large glass of water and food.

This will help to avoid irritating the lining of your oesophagus (food pipe) and stomach.

Swallow the capsules whole with a large glass of water.

Do not open or crush the capsules unless you have difficulty in swallowing (e.g. in children).

- If you are unable to swallow the capsules, you can open them up and pour the powder into a glass of still water or apple juice.
- If you are a woman who is pregnant or might get pregnant and are trying to open the capsules, you should handle the contents with caution in order to avoid skin-eye contact or inhalation.

You should wash your hands immediately after opening the capsules.

For the best effect, take the medicine at about the same time each day.

Taking them at the same time each day will help you to remember to take them.

How long to take it

Continue taking this medicine every day for as long as your doctor prescribes.

Your doctor will keep a close check on you to make sure you are still benefiting from treatment.

If you forget to take it

Take the missed dose as soon as you remember, then continue with your normal schedule.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26; New Zealand 0800 764 766), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers for these places handy.

While you are taking this medicine

Things you must do

Make sure you follow your doctor's instructions carefully and keep all appointments.

You will need regular follow-up to make sure the treatment is working. Regular blood tests and weight checks can also find side effects before they become serious.

Some children and adolescents taking imatinib may have slower than normal growth. Growth will be monitored at regular visits by your doctor.

Make sure you use a method of contraception to prevent pregnancy during treatment with imatinib. Tell your doctor immediately if you become pregnant while you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctor, dentist or pharmacist who treats you that you are taking this medicine.

Things you must not do

Do not give this medicine to anyone else even if their condition seems to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Avoid drinking grapefruit juice while you are being treated with this medicine.

Grapefruit juice may interact with imatinib and affect how your body uses this medicine.

If you need to take something to treat a headache, cold or other minor aches and pains, try to avoid taking medicines containing paracetamol (e.g. Panadol®, Panadeine®, Codral®, Tylenol®).

Ask your pharmacist to suggest an alternative medicine.

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

This medicine may cause dizziness, light-headedness or drowsiness in some people. Make sure you know how you react to it before you drive a car, operate machinery or do anything that could be dangerous.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with this medicine.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- swelling of fingers, eyelids, face or lower legs due to fluid build-up (see your doctor immediately if fluid build-up is severe)
- indigestion, upset stomach, wind, feeling of bloating
- nausea (feeling sick) or vomiting
- diarrhoea
- constipation
- dry mouth
- swelling, aching, cramping or stiffness in joints or muscles
- pain in the bones or along veins
- headache
- dizziness, light-headedness or vertigo (spinning sensation)

- tiredness, weakness, feeling generally unwell
- numbness, coldness or tingling in fingers and toes
- difficulty sleeping, feeling anxious, depressed, confused or forgetful
- change in sense of taste
- rash, eczema, itching, dry skin, darkening or lightening of skin
- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which happens more quickly than normal
- irritated, red, runny or itchy eyes, blurred vision
- ringing in the ears
- changes in appetite and weight
- hair loss
- sweating during the night
- throat pain
- cough or cold symptoms
- loss of interest in sex, problems with sexual function
- breast enlargement, nipple pain, painful periods
- 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

Tell your doctor immediately if you get any of the following side effects:

- severe allergic reaction that can result in difficulty breathing, dizziness.
- rapid weight gain, swelling of the extremities (calves, ankles), generalised swelling such as swelling of the face (signs of water retention)
- weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, swollen glands, sore throat or mouth ulcers (signs of low level of blood cells)
- pale skin, tiredness, breathlessness, dark urine (signs of breakdown of red blood cells).
- pain and having difficulty walking
- cough, difficult or painful breathing, wheezing, pain in chest when breathing (signs of lung infections/disorders).
- muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood).
- muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles (signs of muscle disorders)
- severe abdominal pain, vomiting blood, black or bloody stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain (signs of gastrointestinal disorders)
- thirst, weight loss and severely decreased urine output (signs of low intake of drinks/fluids)
- nosebleeds or any other unusual bleeding
- vision impairment, blurred vision, blood in eye
- nausea, loss of appetite, dark coloured urine or yellowing of your skin or eyes (signs of liver disorders).

- nausea, diarrhoea, vomiting, abdominal pain, fever (signs of inflammatory bowel disease).
- severe rash, red skin, blistering of the lips, eyes, skin or mouth, skin peeling, fever, red raised or purple skin patches, itching, burning, pustular eruption (signs of skin disorder).
- severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands, stomach pain or aching joints and muscles
- inflammation of the skin caused by an infection (sign of cellulitis)
- blood in the urine
- severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system disorder such as bleeding or swelling in the brain)
- seizures (fits)
- swelling and pain in one part of the body (signs of clots in blood vessels)
- crushing chest pain, fever, tiredness, irregular heart beat (signs of heart disorders such as heart attack, angina).
- muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood)
- pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding, (signs of gynaecological disorder)
- nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory (such as high potassium, uric acid, and phosphorous levels and low calcium levels in the blood)
- severe headache, dizziness, blurred vision (signs of increased pressure inside skull).

The above side effects may be serious. You may need urgent medical attention.

Tell your doctor, nurse or pharmacist if you notice any other effect that is making you feel unwell.

Other side effects not listed here or not yet known may happen in some people. Some of these side effects can only be found by laboratory testing.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it

The medicine will not keep as well if taken out of the packaging.

Keep this medicine in a cool dry place where the temperature stays below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What IMATINIB APOTEX looks like

IMATINIB APOTEX 50 mg capsules are off-white to brownish yellow colour granular powder filled in light yellow to orange yellow opaque Size '4' Hard Gelatin capsule imprinted with 'RDY' on cap and '50' on body with red ink.

IMATINIB APOTEX 100 mg capsule is an off-white to brownish yellow colour granular powder filled in an orange to grayish-orange opaque size '1' hard gelatin capsule imprinted with 'RDY' on cap and '100' on body with red ink

IMATINIB APOTEX 400 mg capsule is an off-white to brownish yellow colour granular powder filled in a very dark yellow to brownish-orange opaque size '00' hard gelatin capsule imprinted with 'RDY' on cap and '400' on body with red ink.

Ingredients

Each IMATINIB APOTEX capsule contains 50 mg, 100 mg or 400 mg of imatinib mesilate as the active ingredient.

It also contains the following inactive ingredients:

- crospovidone
- sodium stearyl fumarate
- gelatine
- water
- sodium lauryl sulphate
- titanium dioxide
- iron oxide red
- iron oxide yellow
- iron oxide red (100 mg and 400 mg capsules only)
- iron oxide black (400 mg capsule only)

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

IMATINIB APOTEX 50 mg is available in blister packs of 30 capsules.

IMATINIB APOTEX 100 mg is available in blister packs of 60 capsules.

Imatinib APOTEX 400 mg is available in blister packs of 30 capsules.

Not all strengths and pack sizes may be available.

Australian Registration Numbers

IMATINIB APOTEX 50 mg capsules:
AUST R 261059

IMATINIB APOTEX 100 mg capsules:
AUST R 261054

IMATINIB APOTEX 400 mg capsules:
AUST R 261060

Sponsor

Dr. Reddy's Laboratories (Australia) Pty Ltd
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Melbourne, VIC 3004
Australia

Distributor

Apotex Pty Ltd
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