

- Pain in your eyes (optic neuritis)
- A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)
- Hearing impairment/ hearing loss
- Ringing in the ears (tinnitus)
- You get a rash or skin discolouration with or without raised areas which often reoccurs at the same location each time the drug is taken

PRESENTATION:

Gramex Tablet 400 mg: In blister pack of 10 x 10 Tablets.

STORAGE

Store below 30°C, protect from light.
To be dispensed on the prescription of registered medical practitioner only.
Keep out of reach of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Note: Product contains lactose.

نوٹ: پروڈکٹ میں لیکٹوز شامل ہے۔

Manufactured by:

Platinum
Pharmaceuticals (Pvt) Ltd.
A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

QAR No. AW21-0846

Gramex
(Metronidazole)
400 mg Tablets

گرامیکس
(میٹرونیڈازول)
۴۰۰ ملی گرام گولیاں

COMPOSITION

Gramex 400 mg Tablets

Each tablet contains:

Metronidazole 400 mg

Product Complies U.S.P. Specs.

WHAT GRAMEX IS AND WHAT IT IS USED FOR

The name of this medicine is Gramex 400mg Tablets. Gramex contains a medicine called metronidazole. This belongs to a group of medicines called antibiotics. It works by killing bacteria and parasites that cause infections in your body. It can be used to:

- Treat infections of the blood, brain, lungs, bones, genital tract, pelvic area, stomach and intestines
- Treat gum ulcers and other dental infections
- Treat infected leg ulcers and pressure sores
- Prevent infections after surgery

If you need any further information on your illness, speak to your doctor.

BEFORE YOU TAKE GRAMEX

Do not take Gramex and tell your doctor if:

- You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients in your medicine (listed in Section 6: Further information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take Gramex if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Gramex.

Take special care with Gramex and check with your doctor or pharmacist before using your medicine if:

- You have or have ever had a liver problem.
- You are having kidney dialysis (see section 3: 'People having kidney dialysis')
- You have a disease of the nervous system

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking your medicine. Do this even if they have applied in the past.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with Gramex.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with Gramex and afterwards.

Tell your doctor immediately and stop taking Gramex if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Gramex can affect the way some other medicines work. Also, some other medicines can affect the way Gramex works.

In particular tell your doctor if you are taking any of the following medicines:

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital or phenytoin for epilepsy

- 5 fluorouracil for cancer
- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin – to prevent the rejection of organs after transplant
- Disulfiram for alcoholism

If you are not sure, talk to your doctor or pharmacist before taking Gramex.

Taking Gramex with food and drink

Do not drink any alcohol while you are taking Gramex and for 48 hours after finishing your course. Drinking alcohol while using Gramex might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

Pregnancy and breast-feeding

Tell your doctor before using Gramex if:

- You are pregnant, might become pregnant or think you may be pregnant. Gramex should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to use Gramex if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Driving and using machines

While taking Gramex you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

Tests

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

HOW TO TAKE GRAMEX

Taking your medicine

Always take Gramex exactly as your doctor has told you. It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.

Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets whole with a drink of water
- Do not crush or chew the tablets
- Take these tablets during or just after a meal
- The dose of Gramex will depend on your needs and the illness being treated
- The length of your treatment will depend on the type of illness you have and how bad it is

The usual dose for adults and children is given below:

To treat bacterial infection

Adults

- The initial dose is 800mg
- After 8 hours take another dose of 400mg and repeat this dose every 8 hours

Children

- Your doctor will work out how much your child should take depending on their weight
- Repeat the dose every 8 hours
- If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly

To prevent infections from happening after surgery

Adults

- Start Taking Gramex Tablets 24 hours before your operation
- Take 400 mg of Gramex every 8 hours
- After the operation you may be given Gramex either through a drip into a vein or rectally as a suppository until you are able to take tablets again

Children

- Give your child Gramex Tablets 1-2 hours before their operation
- Your doctor will work out how much your child should take depending on their weight
- After the operation your child may be given Gramex either through a drip into a vein or rectally as a suppository until they are able to take tablets again

Other types of infections

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much Gramex you need to take and how often. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you how many tablets to take and how often to take them.

People having kidney dialysis

Kidney dialysis removes Gramex from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

People with liver problems

Your doctor may tell you to use a lower dose or to use the medicine less often.

If you take more Gramex than you should

If you take more Gramex than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the pack and any tablets left with you.

This is so the doctor knows what you have taken, have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you forget to take Gramex

If you forget to take Gramex, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

POSSIBLE SIDE EFFECTS

Like all medicines, Gramex can cause side effects, although not everybody gets them.

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria) This may mean you are having an allergic reaction to Gramex.
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.
- You develop skin rashes with blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose, and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of something called 'Stevens-Johnson Syndrome or toxic epidermal necrolysis'.

Talk to your doctor straight away if you notice the following side effects.

- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. This could be caused by a blood problem.
- Severe stomach pain which may reach through to your back (pancreatitis)

Tell your doctor or pharmacist if you notice any of the following side effects:

Very rare (affects less than 1 in 10 000 people)

- Fits (convulsions)
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- Problems with your eyesight such as blurred or double vision
- Skin rash or flushing
- Headache
- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life-threatening liver failure (hepatocellular liver injury)

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

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs
- Unpleasant taste in the mouth
- Furred tongue
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite
- Fever
- Feeling depressed