APPROVED PATIENT INFORMATION LEAFLET PODAGRA OTC

SCHEDULING STATUS: S2

PODAGRA OTC 0,5 mg tablets

Colchicine

Contains sugar (50,80 mg lactose monohydrate per tablet)

Read all of this leaflet carefully because it contains important information for you

PODAGRA OTC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use PODAGRA OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PODAGRA OTC with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

1. What PODAGRA OTC is and what it is used for

2. What you need to know before you take PODAGRA OTC

3. How to take PODAGRA OTC

4. Possible side effects

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6. Contents of the pack and other information

1. What PODAGRA OTC is and what it is used for

PODAGRA OTC is used for relief of acute attacks of gout in cases of emergency.

2. What you need to know before you take PODAGRA OTC

Do not take PODAGRA OTC

- if you are hypersensitive (allergic) to colchicine or any of the other ingredients of PODAGRA OTC (listed in section 6).
- if you are pregnant.
- if you are breastfeeding your infant.
- if you are suffering from severe liver or kidney impairment.
- if you are undergoing hemodialysis.
- if you have a severe blood disorder.
- if you have kidney or liver problems and you are taking certain medicines (see 'Taking other medicines with PODAGRA OTC')

Warnings and precautions

Take special care with PODAGRA OTC if you:

- have problems with your heart, kidneys, liver or digestive system
- are elderly (aged 65 years or older) and weak
- have a blood disorder.

PODAGRA OTC can be toxic so it is important that you do not exceed the dose.

There is only a slight difference between an effective dose of PODAGRA OTC and an overdose. Therefore, if you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking PODAGRA OTC and immediately contact your health care provider (see also 'POSSIBLE SIDE EFFECTS').

PODAGRA OTC can cause a serious decrease in bone marrow function leading to a decrease in certain white blood cells (agranulocytosis), a decrease in red blood cells and pigment (aplastic anaemia) and/or a low blood platelet count (thrombocytopenia). You should have regular blood tests to monitor any changes.

If you develop symptoms such as fever, inflammation of the mouth, sore throat, prolonged bleeding, bruising or skin problems, stop taking PODAGRA OTC and contact your health care provider immediately. These could be signs that you have a serious blood problem and your health care provider may want you to have blood tests straight away (see also 'POSSIBLE SIDE EFFECTS').

Other medicines and PODAGRA OTC

PODAGRA OTC is available without a doctor's prescription, however, always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

When PODAGRA OTC are taken together with any of the following medicines, side effects due to colchicine toxicity are more likely to occur and these can be serious and life-threatening:

- Certain antibiotics such as azithromycin, clarithromycin, erythromycin and telithromycin (used to treat infections)
- Anti-viral drugs such as ritonavir, atazanavir and indinavir (used to treat HIV infection)
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis)
- Anti-fungal medicines such as ketoconazole, itraconazole and voriconazole
- Certain heart medicines such as verapamil and diltiazem (used to treat high blood pressure or angina) and quinidine (used to treat abnormal heart rhythms).
- Disulfram (used to help treat alcoholism)

If you are taking any of the above medicines, ask your healthcare provider for advice. If you have liver or kidney problems and you are taking any of the above medicines, you should not take PODAGRA OTC.

It is also important to tell your healthcare provider if you are taking any of the following medicines:

- Cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine in your blood
- Tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood
- Digoxin (used to treat certain heart conditions) and 'fibrates' (medicines used to lower cholesterol), as they may increase your risk of a muscle diseases known as 'rhabdomyolysis'

and ‘myopathy’. Taking Colchicine Tablets together with ciclosporin or ‘statins’ also increases your risk of developing these diseases.

Talk to your healthcare provider before taking PODAGRA OTC if you are taking any medicines that may possibly damage your kidneys, liver or blood.

Check with your healthcare provider if you are not sure.

PODAGRA OTC may reduce the amount of vitamin B12 that your body can absorb through your gut. You may need to take extra vitamin B12 if you have to take PODAGRA OTC in high doses or for a long time.

PODAGRA OTC with food, drink and alcohol

Grapefruit juice may increase the amount of colchicine in your blood. Therefore, you should not drink grapefruit juice whilst you are taking PODAGRA OTC.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PODAGRA OTC.

Pregnancy

Do not take PODAGRA OTC if you are pregnant. If you become pregnant while you are taking PODAGRA OTC,

stop taking it and inform your doctor.

Breastfeeding

Do not use PODAGRA OTC if you are breastfeeding.

Driving and using machines

The possibility of drowsiness and dizziness should be taken into account. If affected, do not drive or operate machinery.

PODAGRA OTC contains lactose monohydrate

Each PODAGRA OTC tablet contains lactose monohydrate which is a sugar. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance, e.g. galactosaemia, or glucose-galactose malabsorption should not take PODAGRA OTC. Talk to your healthcare provider, if you have had an intolerance to some sugars before taking PODAGRA OTC.

3. How to take PODAGRA OTC

PODAGRA OTC is available without a doctor's prescription, however you should check with your healthcare provider if you are unsure on how many PODAGRA OTC tablets to take.

For the treatment of gout in adults:

- The usual adult dose for the treatment of gout is 1 to 2 tablets at the start of treatment followed by one tablet every two to three hours until relief of pain is obtained.
- If you are sick or have diarrhoea you should stop taking PODAGRA OTC and tell your healthcare provider.
- You should not take more than 6 tablets as a course of treatment (your healthcare provider will advise you).
- You should wait three days before starting another course of PODAGRA OTC tablets.

For prevention of the recurrence of gout in adults:

- The dose may range from 1 tablet weekly to three times daily.

For elderly patients or patients with kidney problems:

Consult your doctor first to suggest the appropriate dose.

Method of administration

PODAGRA OTC should be swallowed whole with a glass of water.

Duration of administration

Your healthcare provider will tell you for how long you should take PODAGRA OTC.

If you take more PODAGRA OTC than you should

In the event of an over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

PODAGRA OTC tablets can be seriously toxic. Early symptoms of overdose may include nausea, vomiting, stomach pain, bloody diarrhoea and low blood pressure.

If you forget to take PODAGRA OTC

If you forget to take a dose take another as soon as you remember. If it is almost time for your next dose do not take the missed dose at all. Do not take a double dose to make up for a missed one.

4. Possible side effects

PODAGRA OTC can have side effects.

Not all side effects reported for PODAGRA OTC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PODAGRA OTC, please consult your healthcare provider for advice.

If any of the following happens, stop taking PODAGRA OTC and tell your healthcare provider immediately or go to the casualty department at your nearest hospital:

- fever, a feeling of burning or rawness in the mouth (i.e. stomatitis) and throat making swallowing difficult, prolonged bleeding, bruising or skin problems (see ‘Take special care with PODAGRA OTC’)
- feeling or being sick (i.e. nausea or vomiting)
- diarrhoea with blood in it
- severe stomach pain

- being unable to pass water.

These are all serious side effects. You may need urgent medical attention.

The following side effects are less frequent. Tell your healthcare provider if you notice any of the following:

- blood disorders
- inflammation of the nerves which can cause pain, weakness, numbness and ‘pins and needles’
- liver damage
- rash
- hair loss
- muscle loss
- muscle cramps or weakness
- kidney damage
- the reduced ability to produce sperm
- absence of menstrual periods
- painful periods.

If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PODAGRA OTC**.**

5. How to store PODAGRA OTC

12 tablets in blister packs:

- Store all medicines out of reach of children

- Store at or below 30 °C in the original [container] blister strip in the outer carton, until required for use.
- Do not use after the expiry date stated on the blister strip or outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PODAGRA OTC contains

The active substance is colchicine 0,5 mg.

The other ingredients are: povidone, pregelatinised starch, stearic acid, talc and lactose monohydrate.

What PODAGRA OTC looks like and contents of the pack

Round, white to pale yellow coloured tablets, plain on both sides.

12 tablets in blister packs with strips of white opaque PA/aluminium/PVC film and 25µ aluminium foil of 6 or 12 tablets per blister strip. The blister strips are packed in cartons.

Not all pack sizes may be marketed.

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This leaflet was last revised in

02 September 2022

Registration number

50/3.3/1036