PATIENT INFORMATION LEAFLET FOR KOLCRYS

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

KOLCRYS tablets.

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

KOLCRYS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take **KOLCRYS** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **KOLCRYS** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT KOLCRYS CONTAINS

Active ingredient:
Each **KOLCRYS** tablet contains 0,5 mg colchicine.

Inactive ingredients:
Lactose monohydrate, povidone, pregelatinised starch, stearic acid, talc.

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

2. WHAT KOLCRYS IS USED FOR

KOLCRYS is used to treat acute gout attacks in cases of an emergency.

3. BEFORE YOU TAKE KOLCRYS

Do not take KOLCRYS:

- If you are hypersensitive (allergic) to colchicine or any of the other ingredients of **KOLCRYS**

(see **WHAT KOLCRYS CONTAINS**).

- If you are pregnant (see **pregnancy and breastfeeding**).
- If you have kidney or liver problems.
- If you have any blood disorders.
- If you are on kidney dialysis.

Take special care with KOLCRYS:

- If you are an elderly person.

Tell your doctor:

- If you are or become weak, exhausted or worn out.
- If you develop problems with your heart, kidneys, liver or digestive system.

Taking KOLCRYS with food and drink:

KOLCRYS can be taken with or without food.

Do not take grapefruit juice while taking **KOLCRYS**.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **KOLCRYS**.

Driving and using machinery:

It is not known if **KOLCRYS** can affect your ability to drive a vehicle and use machines. Take special care before performing tasks requiring your attention, until you know how **KOLCRYS** will affect you.

Important information about some of the ingredients of KOLCRYS:

KOLCRYS contains a sugar called lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking **KOLCRYS**.

Taking other medicines with KOLCRYS:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently using:

- Clarithromycin, telithromycin, erythromycin (antibiotics used to treat infections).
- Ritonavir, atazanavir (anti-viral medicine, used to treat human immunodeficiency virus (HIV) infections).
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis).
- Itraconazole, ketoconazole (used to treat fungal infections).
- Verapamil, diltiazem (used to treat high blood pressure or angina).
- Quinidine, digoxin (used to treat abnormal heart rhythms).
- Statins, fibrates (used to treat high cholesterol).
- Hydrochlorothiazide (used to treat high blood pressure).
- Vitamin B_{12} supplement (as **KOLCRYS** may reduce the amount of Vitamin B_{12} that your body can absorb).
- Cimetidine (used to reduce stomach acid).
- Tolbutamide (used to control blood sugar).

4. HOW TO TAKE KOLCRYS

Always take **KOLCRYS** exactly as your pharmacist has instructed you. You should check with your pharmacist if you are unsure.

The usual initial dose is 1 or 2 tablets orally, followed by 1 tablet every two hours until pain relief is obtained or until vomiting (being sick) or diarrhoea starts.

You should not take more than 12 tablets as a course of treatment.

You should wait for 3 days before starting another course of **KOLCRYS**.

If you are an elderly patient or your kidneys are not functioning normally, you will need a lower dose or increased interval between doses.

If you have the impression that the effect of **KOLCRYS** is too strong or too weak, tell your doctor or pharmacist.

If you take more KOLCRYS than you should:

In the event of an overdose consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

KOLCRYS is extremely toxic in overdose, and you are more at risk of toxicity if you have kidney or liver damage, gastrointestinal or heart problems or if you are elderly.

Symptoms:

Symptoms of overdose may not appear for at least 6 hours.

The first symptoms of toxicity are a feeling of burning and rawness in the mouth and throat, and difficulty in swallowing. This is followed by nausea (feeling sick), vomiting (being sick), and diarrhoea which can be severe or bloody leading to dehydration and low blood pressure (you may feel extremely thirsty or faint). A burning sensation of the stomach and skin may also occur. Very serious vascular (vein and artery) damage and kidney toxicity (e.g. abnormal small amounts of urine) may occur. Multiple organ failure may occur and may present as central nervous system (nerve tissues that control the activity of the body) toxicity, bone marrow depression (fever, prolonged bleeding, bruising or skin problems), liver damage, (yellowing of the skin and whites of the eyes, also called jaundice) muscle damage, (pain, swelling, stiffness, weakness) respiratory distress (fast breathing, shortness of breath, or rapid breathing), heart injury (pain in the chest, back, jaw and other areas of the upper body).

You may develop convulsions (fits), delirium (confused thinking), neuropathy (weakness, numbness and pain from nerve damage, usually in the hands and feet), paralysis or sepsis (condition caused

by the body's response to an infection). Hair loss, if you previously had leucocytosis (a condition where you have too many white blood cells) it may return, and stomatitis (inflammation of the mouth and lips) may occur about 10 days after the overdose.

Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

5. POSSIBLE SIDE EFFECTS

KOLCRYS can have side effects.

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

If any of the following happens, stop taking **KOLCRYS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **KOLCRYS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- Gastrointestinal haemorrhage (loose stool with blood in it).
- Kidney damage (passing less urine than is normal).
- Liver damage (yellowing of the skin and whites of the eyes, also called jaundice).
- Problems with your bone marrow which can lead to fever, prolonged bleeding, bruising or skin problems, fatigue, frequent infections or rapid heart rate.

- A breakdown of muscle tissue which can lead to kidney problems. Symptoms include dark, reddish urine, a decreased amount of urine, weakness and muscle aches.

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

Tell your doctor if you notice any of the following:

Frequent:

- Stomach pain.
- Nausea (feeling sick).
- Vomiting (being sick).
- Diarrhoea.

Frequency unknown:

- Weakness, numbness and pain from nerve damage, usually in the hands and feet.
- Hair loss.
- Rash.
- Burning sensation of the skin.
- Muscle weakness.
- Absence of menstrual periods or painful menstrual periods.
- Reduced ability to produce sperm, or a low or zero sperm count.
- Burning sensation in the throat.

6. STORING AND DISPOSING OF KOLCRYS

- Store at or below 30 °C.
- Protect from light and moisture.
- Do not remove blister strips from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Do not use after the expiry date stated on the carton/blister.
- Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF KOLCRYS

Silver Alu/Alu blister strips with 6 tablets per blister strip, provided in outer cartons of 1 x 6 or 2 x 6, therefore a pack of either 6 or 12 tablets.

8. IDENTIFICATION OF KOLCRYS

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

9. REGISTRATION NUMBER

50/3.3/0484

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Forrester Pharma (Pty) Ltd
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11. DATE OF PUBLICATION

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