1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ASPEN COLCHICINE 0,5 mg tablets

Colchicine

Contains sugar: Lactose 64,8 mg

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ASPEN COLCHICINE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What ASPEN COLCHICINE is and what it is used for
2. What you need to know before you take ASPEN COLCHICINE
3. How to take ASPEN COLCHICINE
4. Possible side effects
5. How to store ASPEN COLCHICINE
6. Contents of the pack and other information

1. What ASPEN COLCHICINE is and what it is used for

ASPEN COLCHICINE belongs to a group of medicines called anti-gout medicines. ASPEN COLCHICINE is used for the relief of acute attacks of gout in cases of emergency.

ASPEN COLCHICINE is not a painkiller and should not be used to treat other causes of pain.

2. What you need to know before you take ASPEN COLCHICINE

Do not take ASPEN COLCHICINE:

- If you are hypersensitive (allergic) to colchicine or any of the other ingredients of ASPEN COLCHICINE (listed in section 6).
- If you are pregnant.
- If you are breastfeeding your baby.
- If you have blood dyscrasias (disorders) a medical condition (haematologic disorders) that may affect the cellular or plasma components of the blood, the bone marrow, or the lymph tissue. Examples of blood dyscrasias include anaemias (decrease in the production of your red blood cells), cancers such as leukaemias and lymphomas, conditions that cause the blood to clot or bleed too readily, and more. Symptoms of blood disorders include fever, sore throat, bleeding for a longer than usual time, inflammation of your mouth, bruising or abnormal skin rashes and abnormal tiredness (see section 4 Possible side effects)
- If you are a female of childbearing potential, unless you are using and effective contraceptive.
- If you have liver problems.
- If you have kidney problems.

- If you are undergoing haemodialysis, a procedure in which a machine filters and cleans your blood instead of your kidneys.

- If you are taking a medicine called pristinamycin for the treatment of bacterial infections.
- If you have kidney or liver problems and you are taking certain medicines (see Other medicines and ASPEN COLCHICINE). Examples of these medicines are:
  - Medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole.
  - Medicines used to manage HIV (human immunodeficiency virus) infections such as ritonavir, atazanavir and indinavir.
  - Medicine used to suppress your immune system after an organ transplant such as ciclosporin.
  - Medicine used to treat high blood pressure such as verapamil and diltiazem.
  - Medicine used to treat alcoholism, disulfiram.
- If you are taking a macrolide antibiotic for the treatment of bacterial infection such as clarithromycin, azithromycin and telithromycin.

Warnings and precautions

You should not take more ASPEN CHOLCHICINE than prescribed to you as fatal overdoses have been reported with ASPEN COLCHICINE in adults and children. Keep ASPEN COLCHICINE away from children (see If you take more ASPEN COLCHICINE than you should).

Take special care with ASPEN COLCHICINE if you:

- Have problems with your heart, kidneys, liver or digestive system.
- Are elderly (≥ 65 years) and weak.

- Have a blood disorder as ASPEN COLCHICINE can be toxic. It is important that you **do not exceed the recommended dose.** There is only a slight difference between an effective dose of ASPEN COLCHICINE and an overdose. Therefore, if you get

symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking ASPEN COLCHICINE and immediately contact your doctor (see also section 4 'Possible side effects'). ASPEN COLCHICINE 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 ASPEN COLCHICINE and contact your doctor immediately. These could be signs that you that you have a serious blood problem and your doctor may want you to have blood tests straight away (see Possible side effects).

- Are very tired, weak, with impaired energy or strength or run down (debilitated).
- Start feeling sick, queasy or feel that you are about to vomit (nausea), or if you vomit, feel stomach pain or have loose stools (diarrhoea) after taking ASPEN COLCHICINE then you should stop taking ASPEN COLCHICINE.
- Experience side effects of the digestive system, your healthcare provider will decide either to withdraw ASPEN COLCHICINE or to reduce the dose.

If you are unsure whether you should take ASPEN COLCHICINE discuss it with your healthcare provider.

Children

There is no experience with the use of ASPEN COLCHICINE in children.

Other medicines and ASPEN COLCHICINE

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

Also see Do not take ASPEN COLCHICINE above for medicines that should not be taken together with ASPEN COLCHICINE:

- Medicines used to treat bacterial infections such as clarithromycin, erythromycin, telithromycin and pristinamycin.
- Medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole.
- Medicines used to manage HIV (human immunodeficiency virus) infections such as ritonavir, atazanavir and indinavir.
- Medicine used to suppress you immune system after an organ transplant such as ciclosporin.
- Medicine used to treat high blood pressure such as verapamil and diltiazem.
- Medicine used to treat alcoholism, disulfiram.

Tell your doctor if you are taking any of the following:

- Anti-inflammatory medicines called Non-steroidal anti-inflammatory drugs (NSAIDs) (medicines used to treat inflammation) e.g. ibuprofen, diclofenac.

- Medicines used to treat neoplasms or cancer (abnormal growths of tissue) as concomitant use may increase the concentration of acid in your blood and decrease the effect of gout therapy.
- ASPEN COLCHICINE can cause muscle weakness (myopathy) and the breakdown of muscle fibre (rhabdomyolysis) when co-administered with:

- Medicines used to treat high cholesterol, referred to as statins and fibrates e.g. simvastatin, fluvastatin, pravastatin, atorvastatin, bezafibrate.
- Digoxin (used to treat certain heart conditions).
- Medicine used to suppress you immune system after an organ transplant such as ciclosporin.

You should report any muscle pain or weakness to your doctor immediately (see section 4 Possible side effects).

- Oral blood thinning medications as more frequent INR checks are required. Possible modification of the dosage of the blood thinning treatment is required with ASPEN COLCHICINE and for 8 days after its cessation may be required.
- Cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine, as contained in ASPEN COLCHICINE, in your blood.
- Tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood.
- Talk to your doctor before taking ASPEN COLCHICINE if you are taking any medicines that may possibly damage your kidneys, liver or blood.
- ASPEN COLCHICINE may reduce the amount of vitamin B12 that your body can absorb through your gut.

- Water tablets such as chlorthalidone, hydrochlorothiazide, indapamide used in the management of high blood pressure.

ASPEN COLCHICINE with food

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

Do not consume alcohol while taking ASPEN COLCHICINE.

Pregnancy, breastfeeding and fertility

You must not take ASPEN COLCHICINE if you are pregnant or breastfeeding your baby.

Always tell your healthcare provider if you are taking any other medicine.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ASPEN COLCHICINE.

Driving and using machines

ASPEN COLCHICINE is not expected to influence your ability to drive or operate machinery. It is not always possible to predict to what extent ASPEN COLCHICINE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASPEN COLCHICINE affects you (see section 4).

ASPEN COLCHICINE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ASPEN COLCHICINE.

3. How to take ASPEN COLCHICINE

Do not share medicines prescribed for you with any other person.

Always take ASPEN COLCHICINE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE (see Warnings and precautions)

In acute gout the initial dose is 0,5 mg to 1 mg (1 to 2 tablets) by mouth immediately, followed by 0,5 mg (1 tablet) every 2 hours until pain relief is obtained or gastrointestinal symptoms like vomiting or diarrhoea occur. **A maximum total treatment course of 6 mg (12 tablets) must not be exceeded.**

The course should not be repeated within 3 days, but 7 days should preferably elapse between courses of gout treatment with ASPEN COLCHICINE to avoid cumulative toxicity.

ASPEN COLCHICINE is not a pain medication and should not be used to treat pain from other causes.

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

If you take more ASPEN COLCHICINE than you should

If you take more ASPEN COLCHICINE than you should it can be serious, toxic and even fatal. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you have kidney, liver, digestive tract or heart diseases, or are a very young or an elderly patient you are at particular risk to develop ASPEN COLCHICINE toxicity.

There is often a delay of up to 6 hours before toxicity is apparent; some features may be delayed up to 1 week or longer. Early features (which occur up to 1 day after ingestion but 3 hours on average) include:

- Nausea, vomiting, abdominal pain, low blood pressure, and diarrhoea which may be bloody. Diarrhoea can cause severe loss of fluids which can lead to an emergency condition in which severe blood and fluid loss make the heart unable to pump enough blood to the body.

Symptoms occurring after 1 to 7 days include:

- Confusion
- Decreased heart output, the heart may beat too fast or too slow and difficulty in breathing may be experienced
- Kidney or liver problems
- Problems with breathing
- Extreme elevation of body temperature
- Bone marrow depression, e.g. low white blood cell count.

Also see section 4 Possible side effects.

If you forget to take ASPEN COLCHICINE

Do not take double dose to make up for forgotten individual doses.

4. Possible side effects

ASPEN COLCHICINE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and 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 reaction to ASPEN COLCHICINE. 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:

- Diarrhoea, nausea, vomiting, burning of the throat and stomach pain as this can be signs of toxicity.

- Muscle weakness, low urine output, fatigue, muscle stiffness or soreness/aching/tenderness, bruising, dark, tea-coloured urine, infrequent urination, a fever. As these may be symptoms of damage to muscles (rhabdomyolysis).
- Unusual bleeding or bruising, black tarry stools, blood in urine or stools, pinpoint red spots on the skin as this can be an indication of thrombocytopenia (lowered blood platelets).
- Mild numbness in fingers and toes.

- A severe decrease in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia).
- Unusual tiredness or weakness, headache, difficulty in breathing (usually associated with increased physical activity).
- Fever with or without chills; sores, ulcers, or white spots on the lips or in the mouth, sore throat as this can be an indication of bone marrow depression with agranulocytosis (lowered white blood cells).
- A reduced amount of urine, swelling of your legs, ankles, and feet from retention of fluids caused by the failure of the kidneys to eliminate water waste, unexplained shortness of breath, excessive drowsiness or fatigue as these may be symptoms of renal damage.
- Perfuse diarrhoea with blood in stools.
- Yellowing of the whites of the eyes and skin accompanied by nausea, severe stomach pain and swelling of the legs as this can be a sign of liver damage (hepatotoxicity).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea, vomiting, abdominal pain and diarrhoea.

Side effects with an unknown frequency:

- Burning of the skin, skin rashes, hair loss (alopecia);
- lack of fluids (dehydration);
- lowered blood pressure;

- absence of menstrual periods;
- painful periods;
- reduced ability to produce sperm (low or zero sperm count).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ASPEN COLCHICINE.

5. How to store ASPEN COLCHICINE

Store at or below 25 °C, in airtight containers.

Protect from light.

Store all medicines out of reach of children.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 ASPEN COLCHICINE contains

Each tablet of ASPEN COLCHICINE contains 0,5 mg of colchicine.

The other ingredients are gelatin, lactose monohydrate, magnesium stearate, purified talc, starch maize.

Contains sugar: Lactose monohydrate 64,8 mg

What ASPEN COLCHICINE looks like and contents of the pack

White, round, biconvex tablet bisected on one side and plain on the other side.

12 tablets are packed in a white polypropylene container and sealed with a white low density polyethylene snap-on cap together with a white foam insert or rayon coil. The container is packed with a leaflet.

12 tablets are packed in a PVC blister with aluminium foil backing. There are 6 tablets per blister strip and two blisters strips are packed together with a leaflet into a unit carton.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

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C0822 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9309515 S2

Namibia: NS1 14/3.3/0214

Zimbabwe: P.I.M. 95/3.2/2993

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