1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

ASPEN COLCHICINE DS

Tablets

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ASPEN COLCHICINE DS 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 after 7 days.

WHAT ASPEN COLCHICINE DS CONTAINS

Each tablet of ASPEN COLCHICINE DS contains 1,0 mg of colchicine.

The other ingredients are:

Gelatin, lactose monohydrate, magnesium stearate, maize starch, talc.

Contains sugar: Lactose monohydrate 129,60 mg

WHAT ASPEN COLCHICINE DS IS USED FOR

ASPEN COLCHICINE DS is used for the emergency treatment of acute gout attacks.

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

BEFORE YOU TAKE ASPEN COLCHICINE DS

Do not take ASPEN COLCHICINE DS if you are:

- Hypersensitive (allergic) to colchicine or any of the other ingredients of ASPEN COLCHICINE DS (see WHAT ASPEN COLCHICINE DS CONTAINS).
- Patients with lactose intolerance should avoid this product as it contains lactose monohydrate (see WHAT ASPEN COLCHICINE DS CONTAINS).
- Pregnant.
- Undergoing haemodialysis.
- Suffering from severe kidney impairment.
- Suffering from any severe liver impairment and taking the following medicines:
    - Clarithromycin, erythromycin or telithromycin (used to treat infections).
    - Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis).
    - Ritonavir, atazanavir or indinavir (used to treat HIV infection).
    - Ketoconazole or itraconazole (used to treat fungal infections).
    - Verapamil and diltiazem (used to treat high blood pressure or angina).
    - Quinidine (used to treat abnormal heart rhythms).
- If you have blood disorders as ASPEN COLCHICINE DS can cause a decrease in production of your red blood cells, white blood cells and blood platelets.

Take special care with ASPEN COLCHICINE DS

- If you are an elderly (≥ 65 years) or debilitated patient (a patient with impaired energy or strength) as you may be prone to the toxicity of ASPEN COLCHICINE DS. Your healthcare provider will be monitoring you for toxicity and may decide to temporarily interrupt or discontinue your treatment with ASPEN COLCHICINE DS. The first signs of toxicity are nausea, vomiting and diarrhoea.
- If you experience adverse effects in the digestive system, your doctor will decide either to withdraw ASPEN COLCHICINE DS or to reduce the dose.
- ASPEN COLCHCINE DS can cause nerve and muscle toxicity (see POSSIBLE SIDE EFFECTS). If you need to take other medicines known to cause the same effect/s e.g. ciclosporin (used in organ transplants) and HMG-CoA reductase inhibitors such as simvastatin (used to treat high cholesterol) your doctor will monitor you.

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

Taking/Using ASPEN COLCHICINE DS with food and drink

ASPEN COLCHICINE DS may be given at any time of the day, with or without food.

Alcohol increases blood uric acid concentrations and increases the risk of digestive tract disorders.

Pregnancy and breastfeeding

You should not take ASPEN COLCHICINE DS if you are pregnant.

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

If you are pregnant or breastfeeding, please consult your healthcare provider for advice

before taking ASPEN COLCHICINE DS.

Driving and using machinery

ASPEN COLCHICINE DS is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ASPEN COLCHICINE DS does not adversely affect your ability to do so safely (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients in ASPEN COLCHICINE DS

ASPEN COLCHICINE DS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ASPEN COLCHICINE DS.

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

Taking other medicines with ASPEN COLCHICINE DS

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

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

- Clarithromycin, erythromycin or telithromycin (used to treat infections) (see Do not take ASPEN COLCHICINE DS).
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis) (see Do not take ASPEN COLCHICINE DS).
- Ritonavir, atazanavir or indinavir (used to treat HIV infection) (see Do not take ASPEN COLCHICINE DS).
- Ketoconazole or itraconazole (used to treat fungal infections) (see Do not take ASPEN

COLCHICINE DS).

- Verapamil and diltiazem (used to treat high blood pressure or angina) (see Do not take ASPEN COLCHICINE DS).
- Digoxin (used to treat irregular heartbeat).
- Anti-inflammatory medicines e.g. ibuprofen, diclofenac (used to treat inflammation).
- Medicines that can cause blood disorders like antibiotics e.g. chloramphenicol and co-trimoxazole, anti-psychotics e.g. clozapine and olanzapine, anti-thyroid medicines e.g. carbimazole and anti-epileptics e.g. lamotrigine, phenytoin, valproic acid and carbamazepine.
- Vitamin B_{12} - absorption of this vitamin may be impaired by chronic administration of ASPEN COLCHICINE DS and you may require higher doses of vitamin B_{12}.
- Statins and fibrates e.g. simvastatin, fluvastatin, pravastatin, atorvastatin, bezafibrate (used to lower cholesterol).
- Water tablets such as chlorthalidone, hydrochlorothiazide, indapamide (used to treat high blood pressure).
- Anticoagulants such as warfarin used to thin blood.

HOW TO TAKE ASPEN COLCHICINE DS

Always take ASPEN COLCHICINE DS exactly as your healthcare provider has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

Dosage

Your healthcare provider will decide on the appropriate dose for you, based on your condition.

Acute attacks of gout in adult patients:

Take 1 mg (one tablet) immediately, followed by 0,5 mg (half a tablet) 2 hourly until pain is relieved or until vomiting or diarrhoea occur.

A maximum dosage of 6 mg (six tablets) must not be exceeded.

A minimum of 3 days, but preferably 7 days, should elapse between courses of gout treatment with ASPEN COLCHICINE DS to avoid cumulative toxicity.

If you have severe kidney problems, you should not take ASPEN COLCHICINE DS.

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

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

If you take more ASPEN COLCHICINE DS than you should

Fatal overdoses have been reported with ASPEN COLCHICINE DS in adults and children.

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, go to the nearest hospital or poison control centre.

If you forget to take ASPEN COLCHICINE DS

Take your missed dose as soon as you remember if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

ASPEN COLCHICINE DS can have side effects.

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

If any of the following happens, stop taking ASPEN COLCHICINE DS 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.
- Pale red, raised, itchy bumps on the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASPEN COLCHICINE DS. 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 and stomach pain as this can be signs of toxicity.
- Abnormal urine colour (dark, red, or cola coloured), decreased urine production, general weakness, muscle stiffness or aching, muscle tenderness, weakness of the affected muscles as this can be an indication of rhabdomyolysis (see Take special care with ASPEN COLCHICINE DS).
- 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).

- Unusual tiredness or weakness, headache, difficulty in breathing (usually associated with increased physical activity).
- Unusual bleeding or bruising, black tarry stool, blood in urine or stools, pinpoint red spots on the skin as this can be an indication of thrombocytopenia (lowered blood platelets).
- Vomiting and/or diarrhoea, nausea, weight loss, nocturnal urination (night time urination), more frequent urination as these may be signs of renal problems (renal damage).
- Nausea, loss of appetite, fatigue, diarrhoea, swollen abdomen, yellow colour of the skin and whites of the eyes as these may be signs of liver problems (liver damage).

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Hair loss.

The following side effects have been reported less frequently:

- Mild numbness in fingers and toes.
- Burning of the throat.
- Muscle weakness.
- Inhibition of sperm production.

The following side effects have been reported, but the frequency is unknown:

- Low blood pressure.

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

pharmacist.

STORING AND DISPOSING OF ASPEN COLCHICINE DS

Store at or below 25 °C.

Protect from light.

Keep the blisters in the outer carton 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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ASPEN COLCHICINE DS

6 tablets are packed in an opaque white polyvinylchloride film sealed with silver aluminium foil backing or in an opaque white polyvinylchloride, polyvinylidene chloride film sealed with silver aluminium foil or in an opaque white polyvinylchloride, polyethylene, polyvinylidene chloride film sealed with silver aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs are necessarily marketed.

IDENTIFICATION OF ASPEN COLCHICINE DS

A round, white to off-white flat, bevelled edged tablet, bisected on one side.

REGISTRATION NUMBER

41/3.3/0260

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

PHARMACARE LIMITED

Healthcare Park

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Hotline: 0800 122 912 (South Africa)

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