Clean Proposed Patient Information Leaflet

SCHEDULING STATUS

S2

DEMAZIN COLD and FLU.

Ibuprofen 200 mg and pseudoephedrine hydrochloride 30 mg per tablet.

Sugar free.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share Demazin Cold and Flu with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve in 7 days for treatment of a cold and after 3 days for treatment of a fever.

What is in this leaflet

1. What Demazin Cold and Flu is and what it is used for
2. What you need to know before you take Demazin Cold and Flu
3. How to take Demazin Cold and Flu

4. Possible side effects

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1. What Demazin Cold and Flu is and what it is used for

DEMAZIN COLD & FLU tablets are used for the relief of symptoms associated with the common cold, sinusitis, or flu, such as blocked nose, headache, fever, body aches and pain.

The active substance ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (known as NSAIDs), which reduce fever and relieve pain.

The other active substance pseudoephedrine hydrochloride is a decongestant, which relieves nasal congestion.

2. What you need to know before you take Demazin Cold and Flu

Do not take Demazin Cold and flu

- if you are hypersensitive (allergic) to ibuprofen, pseudoephedrine hydrochloride or any of the other ingredients of Demazin Cold and Flu (see section 6.)
- if you are hypersensitive (allergic) to any other nonsteroidal anti-inflammatory medicine, aspirin or any other pain or fever relieving medicine
- if you have had or are suffering from asthma, recurrent ulcers or bleeding ulcers, any bleeding disorder, heart failure or any heart or blood pressure disorder, a liver disorder or a kidney disorder
- if you have had or are suffering from prostatic hypertrophy (enlargement of the prostate gland), overactive thyroid, diabetes mellitus (sugar diabetes), glaucoma (an eye disease)

- if you are pregnant or breast-feeding (see “Pregnancy and Breastfeeding”)
- you are taking a prescription monoamine oxidase inhibitor (medicine prescribed for depression, psychiatric or emotional conditions or Parkinson’s disease) or if it has been less than 14 days since you have stopped treatment with a monoamine oxidase inhibitor (MAOI).

Demazin Cold and Flu must not be given to children under 12 years.

Warnings and precautions

Take special care with Demazin Cold & Flu:

- If you have trouble sleeping, take the last dose for each day several hours before bedtime.
- Do not drink alcoholic beverages while taking Demazin Cold and Flu, as side effects may be more likely to occur.
- The risk of gastrointestinal bleeding or ulceration is higher with increasing doses, in patients with a history of ulcers and the elderly.
- Serious skin reactions have been reported in association with NSAID therapy. Discontinue treatment at the first appearance of rash or any other sign of hypersensitivity and contact your doctor.
- If you are older than 65 years.
- you are allergic to any other pain or fever relieving medicines, such as aspirin or other NSAIDs (see **“Do not take Demazin Cold and Flu**).

Ask your doctor or pharmacist for advice before taking Demazin Cold and Flu tablets if you have suffered or suffer from any other medical problem, or if you are under a doctor's care for any continuing medical condition, for example:

- asthma, high blood pressure, heart failure or heart disease, fluid retention, hepatitis or other liver disease, kidney disease, diabetes mellitus (sugar diabetes)
- stomach or colon irritation or bleeding, colitis, Crohn's disease, stomach ulcer or other stomach or intestinal problems
- epilepsy, anaemia, systemic lupus erythematosus (SLE) bleeding problems.

Other medicines and Demazin Cold and Flu

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

Medicines that may interact with Demazin Cold and Flu tablets include:

- medicines to reduce the clotting of the blood
- medicines to treat diabetes
- medicines to reduce your blood pressure or medicines to stimulate the heart.
- lithium, methotrexate, corticosteroids, diuretics, quinolones, selective serotonin reuptake inhibitors (a class of antidepressant), alcohol, phenytoin, beta blockers, insulin, oral antidiabetic medicines, antiplatelets such as clopidogrel and ticlopidine
- aspirin, any other product that contains ibuprofen or any other pain or fever relieving medicine

- central nervous system stimulation-producing medicines, levodopa, quinidine, tricyclic antidepressants, halogenated anaesthetics, digitalis, thyroid hormones, citrates, nitrates
- monoamine oxidase inhibitors (see **"Do not take Demazin Cold and Flu tablets"**)
- any other medicine that contains pseudoephedrine hydrochloride or any other decongestant
- mifepristone should not be used for 8 – 12 days after taking Demazin Cold and Flu because it can weaken the effect of mifepristone
- appetite suppressants and medicines called amphetamine-like psychostimulants may increase the risk of elevating blood pressure
- the effect of medicines called anti-cholinergic medicines for example tricyclic antidepressants may be increased.

Pregnancy and breastfeeding

Demazin Cold and Flu should not be used during pregnancy or breastfeeding.

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 health care provider for advice before taking this medicine

Driving and using machines

It is not always possible to predict to what extent Demazin Cold and Flu may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Demazin Cold and Flu affects them.

3. How to take Demazin Cold and Flu

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

Always take Demazin Cold and Flu exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are unsure.

The usual dose for adults and children 12 years and older is

One tablet every 4 to 6 hours. If symptoms do not respond to one tablet, a second tablet may be taken.

Do not take more than 6 tablets in any 24-hour period.

Demazin Cold and Flu should be taken with a glass of water, with food or after meals.

Do not take for a cold for more than 7 days or for fever for more than 3 days, unless directed by a doctor.

If the cold or fever persists or gets worse, or if new symptoms occur, consult a doctor.

Use the lowest effective dose for the shortest possible duration of treatment.

For safe and effective use of Demazin Cold and Flu, do not take more of it, do not take it more often, and do not take it for a longer time than ordered by your health care professional or as directed on the package label.

If you take more Demazin Cold and Flu than you should

In case of accidental overdose, immediately consult your doctor or pharmacist. If neither is available, immediately contact the nearest hospital or poison control centre.

If you forget to take Demazin Cold and Flu

Do not take double doses to make up for forgotten individual does. Continue taking the tablets as directed on the label.

Contact your healthcare professional for further advice.

4. Possible side effects

Demazin Cold and Flu can have side effects.

Not all side effects reported for Demazin Cold and Flu are included in this leaflet. Should your general health worsen of if you experience any untoward effects while taking Demazin Cold and Flu, please consult your health care provider for advice.

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

- fainting
- facial swelling
- fast or irregular breathing
- shortness of breath
- chest pain
- wheezing or tightness in chest
- fast or irregular heartbeat or pulse
- unusual flushing or warmth of the skin
- hive-like swellings on face, eyelids, mouth, lips or tongue

- puffiness or swelling of eyelids.

These are all very serious side effects. If you have them, you may have had a serious reaction to Demazin Cold and Flu. You may need urgent medical attention or hospitalisation.

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

- abdominal or stomach pain
- cramping or burning
- bloody or black stools
- chest pain
- convulsions (seizures)
- fever with or without chills
- severe or continuing nausea or heartburn or indigestion
- sores or ulcers on lips or mouth
- unexplained nosebleeds
- unusual bleeding or bruising
- spitting up blood
- vomiting of blood or material that looks like coffee grounds
- skin rash
- hallucinations

- fever, rash, facial swelling, enlarged glands, which may indicate a severe reaction to Demazin Cold and Flu
- skin rash with formation of pustules (pimple like eruption filled with pus).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- burning feeling in the throat, chest or stomach
- dizziness
- heartburn, indigestion
- nausea
- trouble sleeping
- nervousness, feeling irritable, drowsiness
- restlessness

Less frequent side effects:

- bladder pain
- bloody or cloudy urine
- any problem with urination
- blurred vision or any change in vision
- ringing or buzzing in ears, change in hearing

- bleeding from cuts and scratches that lasts longer than usual
- severe headache
- mood or mental changes; unusual tiredness
- yellow eyes or skin
- general feeling of discomfort or illness
- light-headedness
- bloated feeling, constipation, diarrhoea
- sweating, tremor, muscle weakness
- high blood pressure
- swelling of lower legs and hands

<u>Frequency of side effects unknown:</u>

- sensitivity to light (eyes or skin)
- fear, confusion
- appetite decreased, feeling thirsty
- when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood. This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

If you notice any of the 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 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 Demazin Cold and Flu.

Alternately please contact iNova Pharmaceuticals (Pty) Ltd on 011 087 0000 or www.inovapharma.co.za

5. How to store Demazin Cold and Flu

Store at or below 25 °C. Protect from light and exposure to air.

Store in the original package.

Do not use this medicine after the expiry date shown on the carton.

Store all medicines out of reach of children.

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 Demazin Cold and Flu contains

- The active substances are ibuprofen and pseudoephedrine hydrochloride.
- The other ingredients are anhydrous colloidal silica, croscarmellose sodium, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, magnesium stearate, maize starch, hydroxypropylmethyl cellulose, macrogol 400, talc, pigment (titanium dioxide) and colouring agent (iron oxide yellow).

What Demazin Cold and Flu looks like and contents of the pack

Yellow, round film-coated tablet without breaking score.

Cartons containing blister packs of 10 or 20 tablets per carton.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

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To be allocated.

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