PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

DEMAZIN SYRUP

Chlorphenamine maleate 1,25 mg/5 ml

Phenylephrine Hydrochloride 2,5 mg/5ml

Contains sugar: (sucrose) 550 mg/ml

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DEMAZIN SYRUP 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 after 7 days.

What is in this leaflet

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

1. What DEMAZIN SYRUP is and what it is used for

DEMAZIN SYRUP belongs to a group of medicines called “Preparations for the common cold, including nasal decongestants and antihistaminics”.

DEMAZIN SYRUP provides relief of nasal congestion and other symptoms associated with sinusitis, hay fever, nasal allergies or other respiratory allergies.

2. What you need to know before you take DEMAZIN SYRUP

Do not take DEMAZIN SYRUP:

- if you are hypersensitive (allergic) to chlorphenamine maleate, phenylephrine hydrochloride or any of the other ingredients of DEMAZIN SYRUP (listed in section 6).
- if you are receiving antidepressants called monoamine oxidase inhibitors, or within 14 days of you stopping such treatment.
- if you are pregnant or breastfeeding (see section **Pregnancy, breastfeeding and fertility**).
- if you suffer from severe high blood pressure or coronary heart disease.

DEMAZIN SYRUP should not be given to children under 2 years of age.

Warnings and precautions

Special care should be taken with DEMAZIN SYRUP if you suffer from:

- an overactive thyroid,
- heart disease, such as coronary heart disease,
- irregular heartbeat,

- rapid heartbeat,
- disorders in which narrowed blood vessels reduce blood flow to the limbs (occlusive vascular disorders), including build-up of fats, cholesterol and other substances in and on the artery walls (arteriosclerosis),
- high blood pressure,
- ballooning and weakened area in an artery (aneurysms),
- high blood sugar (diabetes),
- a condition in which the pressure inside of your eye becomes too high, called closed-angle glaucoma,
- an enlarged prostate gland (prostatic hypertrophy),
- a rare tumor of the adrenal glands, which sit above the kidneys, called phaeochromocytoma,
- a lung condition that causes shortness of breath (emphysema),
- chronic bronchitis,
- a disorder resulting from build-up of certain chemicals related to red blood cell proteins, called porphyria.

Special care should be taken with DEMAZIN SYRUP:

- If you are elderly, you will be especially susceptible to dizziness, sedation, confusion, low blood pressure and anticholinergic effects such as dry mouth and difficulty urinating and completely emptying the bladder.
- Do not take DEMAZIN SYRUP for more than 7 days. After 5 to 7 days a sudden decrease in response to the medicine may occur, and the medicine loses effect. If your symptoms do not improve, or are accompanied by fever, consult a doctor.
- Long term use of antihistamines may decrease the flow of saliva and contribute to

development of tooth decay, gum disease, oral thrush and discomfort.

- DEMAZIN SYRUP contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

DEMAZIN SYRUP may cause:

- hyperexcitability (feeling unusually excited),
- nervousness,
- irritability,
- insomnia,

Exceeding the recommended dose may result in:

- nervousness,
- dizziness,
- sleeplessness,
- involuntary shaking or movement,
- or irregular heartbeat.

This may also occur in sensitive individuals at small doses.

Caution should be used when the following medical conditions exist: Severe cardiovascular (heart) disorders, epilepsy and during an acute attack of asthma.

Children

DEMAZIN SYRUP is not recommended:

- In newborn or premature infants. This age group has an increased susceptibility to anticholinergic side effects such as central nervous system excitation and an increased tendency towards convulsions.
- For children who have breathing problems such as chronic bronchitis, or

- Children who have eye conditions that damage the nerves in the eye (glaucoma), without first consulting the child's doctor.
- Children who are taking sedatives and tranquillisers, without first consulting the child's doctor. DEMAZIN SYRUP may cause drowsiness; sedatives and tranquillisers may increase the drowsiness effect.

Other medicines and DEMAZIN SYRUP

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

Medicines that may interact with DEMAZIN SYRUP:

- All sedatives and alcohol increase the central nervous system depressant effects of antihistamines.
- Antidepressants called tricyclic antidepressants or maprotiline (tetracyclic antidepressant) increase anticholinergic effects (ability to block the action of a neurotransmitter) if taken with antihistamines.
- Monoamine oxidase inhibitors (antidepressants) will increase both the drowsiness effect and the anticholinergic effects (such as dry mouth and sedation) if taken with antihistamines. Concurrent use is not recommended.
- The effects of anticholinergics (medicines that block the action of a neurotransmitter called acetylcholine) or medicines with anticholinergic activity will be increased if used together with antihistamines.
- An increased risk of irregular heartbeat may occur if DEMAZIN SYRUP is given to patients receiving cardiac glycosides (medicines for treating heart failure and certain irregular heartbeats), quinidine (medicines used to restore normal sinus rhythm, treat a

heart condition that causes an irregular and often abnormally fast heart rate, and treat abnormal heart rhythms that make the lower chamber of your heart twitch instead of pump) or tricyclic antidepressants.

- Reversal of the action of antihypertensive agents (medicines which lower blood pressure) may occur and therefore special care is advisable if you are receiving antihypertensive therapy.

  Interactions with alpha- and betablockers may be complex and can produce a severe increase in blood pressure that can for example lead to a stroke.
- DEMAZIN SYRUP should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may cause ventricular fibrillation (a type of abnormal heart rhythm).
- The warning signs of damage caused by ototoxic medicines (medicines that develops hearing or balance problems) such as aminoglycoside antibiotics (broad-spectrum, bactericidal antibiotics) may be masked.

Interactions are possible with:

- guanethidine (medicine used to treat high blood pressure),
- reserpine (medicine used to treat high blood pressure),
- tricyclic antidepressants,
- digoxin (medicine used to treat various heart conditions),
- alphamethyldopa (medicine used to treat high blood pressure),

Other interactions

The use of DEMAZIN SYRUP should be discontinued several days prior to skin testing procedures since chlorphenamine maleate may prevent or diminish otherwise positive reactions to skin reactivity indicators.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and breastfeeding has not been established.

DEMAZIN SYRUP is best avoided in pregnancy, because the active substance, Phenylephrine, has the potential to promote uterine contractions and narrowing of the blood vessels, with the possibility of restriction of oxygen to the foetus (see section **2. What you need to know before you take DEMAZIN SYRUP**).

The active substance, Chlorphenamine maleate, may inhibit lactation due to its ability to block the action of a neurotransmitter (anticholinergic effects). Small amounts of antihistamines entering breast milk may cause drowsiness or excitement and/or irritability in infants (see section **2. What you need to know before you take DEMAZIN SYRUP**).

The effect on fertility is unknown.

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

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents e.g. sedatives and tranquillisers. Caution should be used when driving a motor vehicle or operating machinery or performing potentially dangerous tasks, where loss of concentration may lead to accidents.

It is not always possible to predict to what extent DEMAZIN SYRUP 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 SYRUP affects them.

DEMAZIN SYRUP contains sucrose and propylene glycol

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

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your

doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to take DEMAZIN SYRUP

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

Always take DEMAZIN SYRUP exactly as described in this leaflet or as your doctor, or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is as follows:

- Children two to three years: Give 2,5 to 5 ml every three or four hours.
- Three to six years: Give 5 to 10 ml every three or four hours.

  (Refer to section Warnings and precautions)
- Adults: Take 10 ml every three or four hours.

Elderly population

You may need to reduce the dose **(refer to section Warnings and precautions)**.

If you take more DEMAZIN SYRUP than you should

The following are possible signs and symptoms of overdose:

- Drowsiness or paradoxical excitement.
- Impaired coordination.
- Involuntary shaking or moving.
- Movement dysfunction that includes involuntary twisting, squirming movements (athetosis).
- Hallucinations.
- Convulsions.
- Fixed, dilated pupils with blushing.
- Faster heartbeat (Sinus tachycardia).
- Difficult or laboured breathing.
- Difficulty urinating and completely emptying the bladder.
- Dry mouth.
- Fever.
- Terminally there may be deepening coma and sudden, unexpected loss of heart function, breathing and consciousness (cardiorespiratory collapse).
- Severe increase in blood pressure may occur.
- Central excitatory effects (stimulating effect on the neurons) constitute the greatest danger, particularly in children who are more likely to exhibit central nervous system stimulation. Adults more frequently exhibit central nervous system depression and the aged are particularly prone to experience low blood pressure.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact

the nearest hospital or poison centre.

If you forget to take DEMAZIN SYRUP

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

4. Possible side effects

DEMAZIN SYRUP can have side effects.

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

If any of the following happens, stop taking DEMAZIN SYRUP 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,
- fever,
- sudden headache,
- sudden nausea and vomiting,
- narrowing of blood vessels leading to high blood pressure,
- sudden tingling, numbness, weakness or paralysis of face, arm or leg,
- sudden difficulty speaking or walking, loss of balance or problems with coordination,
- excess fluid in the lungs,
- cardiac arrest.

These are all very serious side effects. If you have them, you may have had a serious reaction

to DEMAZIN SYRUP. 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:

- convulsions,
- tight chest,
- palpitations,
- fast heart rate,
- sudden fever, chills, sore throat and weakness, rapid heart rate or rapid breathing (caused by an extremely low number of granulocytes (a type of white blood cell) in the blood),
- coughing up blood or bloody froth,
- difficulty breathing that worsen with activity or when lying down,
- rapid, irregular heartbeat,
- slow heart rate,
- irregular heartbeat,
- palpitations,
- chest pain may be caused if you have a reduced blood flow to your heart (angina pectoris)

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

Tell your doctor if you notice any of the following:

- sedation,
- dizziness,
- fatigue,
- incoordination,

- involuntary shaking or movement,
- confusion,
- blurred vision,
- double vision,
- ringing or buzzing in the ears,
- feeling intense excitement or happiness,
- nervousness,
- tingling,
- weakness of the hands,
- irritability,
- nightmares,
- insomnia,
- hallucinations,
- dryness of the mouth and respiratory passages,
- thickening of mucous,
- cough,
- increased sweating,
- difficulty urinating and completely emptying the bladder,
- change in frequency of urination,
- discomfort, pain or burning when urinating,
- headache,
- low blood pressure,
- loss of appetite,

- nausea,
- vomiting,
- epigastric distress (pain above the stomach, under the ribcage),
- diarrhoea,
- reduction in tone and motility of the gastrointestinal tract, resulting in acid reflux and constipation,
- photosensitisation (extreme sensitivity to ultraviolet rays from the sun and other light sources),
- fatigue, shortness of breath, dizziness, headache, coldness in your hands and feet, pale skin and chest pain caused by a disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia),
- a low level of white blood cells in the blood which can interfere with the ability to fight infection (leukopenia),
- easy or excessive bruising, superficial bleeding into the skin, prolonged bleeding from cuts, bleeding from your gums or nose, blood in urine or stools caused by a low number of platelets in the blood (thrombocytopenia),
- fear,
- anxiety,
- restlessness,
- weakness,
- psychotic states,
- reduced appetite,
- low blood pressure with dizziness and fainting and flushing,
- difficult or laboured breathing,

- altered metabolism, including disturbances of glucose metabolism,
- sweating,
- hypersalivation.

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 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 SYRUP.

5. How to store DEMAZIN SYRUP

Store all medicines out of reach of children.

Store at or below 25 ºC.

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 SYRUP contains

- The active substances are chlorphenamine maleate 1,25 mg and phenylephrine hydrochloride 2,5 mg per 5 mℓ syrup.
- The other ingredients are sucrose 550 mg/ml, glycerin, propylene glycol, methylparaben 0,05 % *m/v,* propylparaben 0,01 % *m/v,* levomenthol, vanillin flavour, benzaldehyde,

peach flavour, dye FD and C blue no. 1, dye FD and C green no. 3, dye FD and C yellow no. 6, hydrochloric acid and purified water.

What DEMAZIN SYRUP looks like and contents of the pack

DEMAZIN SYRUP is a clear, blue syrup with an aromatic odour and sweet taste, free from foreign matter. It is packed in an amber glass bottle of 100 ml.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

This leaflet was last revised in

27 January 2023

Registration number

C535 (Act 101/1965)

Access to the corresponding Professional Information

Full professional Information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.

NAMIBIA

Scheduling Status: NS1

Registration Number: 14/5.8/0376

BOTSWANA

Scheduling Status: S2

Registration Number: BOT1703220A

A7210