PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DEMAZIN FLU, ASCORBIC ACID 125 MG, DEXTROMETHORPHAN HYDROBROMIDE 20 MG, PARACETAMOL 300 MG, PSEUDOEPHEDRINE HYDROCHLORIDE 30 MG, EFFERVESCENT TABLET.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DEMAZIN FLU 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 2 weeks.

WHAT DEMAZIN FLU CONTAINS:

- The active substances are ascorbic acid 125 mg, dextromethorphan hydrobromide 20 mg, paracetamol 300 mg, pseudoephedrine hydrochloride 30 mg.
- The other ingredients are: Aspartame, caramel powder, fumaric acid, lemon flavor, mannitol, povidone, sodium bicarbonate, sodium chloride, sorbitol.

WHAT DEMAZIN FLU TABLET IS USED FOR:

Pharmacotherapeutic group:

Category A: 5.8 Preparations for the common cold, including nasal decongestants and antihistaminics.

Therapeutic indication:

DEMAZIN FLU is used for the relief of symptoms such as cough, nasal congestion, minor fever and pain associated with colds and influenza.

BEFORE YOU TAKE DEMAZIN FLU:

- Inform your doctor and pharmacist if you are allergic to any medicines,
- Inform your doctor if you are pregnant, intend to become pregnant or if you are breastfeeding.
- Inform your doctor if you have severe hypertension, hyperthyroidism, diabetes, glaucoma, heart disease or kidney disease.
- If you are hypersensitive to paracetamol or any of the other ingredients of DEMAZIN FLU.

Do not use DEMAZIN FLU:

- If you are allergic to any of the ingredients.
- Do not use in children below 12 years of age
- Do not take DEMAZIN FLU if you are presently taking monoamine oxidase inhibitors or other medicines for depression, psychiatric or emotional conditions or hypertension.

Take special care with DEMAZIN FLU

Follow the directions for using this medicine provided by your doctor or pharmacist. If symptoms persist consult your doctor. Do not use continuously for more than 10 days without consulting your doctor. Do not remove the tablet from the tube until immediately before use.

Pregnancy and Breastfeeding

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor or other healthcare professional for advice before taking this medicine.

Taking other medication with DEMAZIN FLU

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

HOW TO TAKE DEMAZIN FLU

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

Always take DEMAZIN FLU exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The usual dose is: adults and children over 12 years of age: Dissolve 2 effervescent tablets in a glass of very hot, but not boiling water: drink when still very hot. Repeat with 2 effervescent tablets every 4 hours (maximum 6 tablets in 24 hours).

DEMAZIN FLU is not suitable for children under 12 years of age

If you take DEMAZIN FLU then you should

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

If you forget to take a dose of DEMAZIN FLU

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

DEMAZIN FLU can have side effects.

Table 1: The following side-effects have been reported and the frequencies are unknown	
Blood disorders	Neutropaenia (diminished number of neutrophils in the blood), pancytopaenia (abnormal depression of all the cellular elements of the blood) and leucopaenia (reduction of the number of leukocytes in the blood).

Immune system disorders	Allergic reaction
Metabolism and nutrition disorders	Altered metabolism (including glucose metabolism)
Psychiatric disorders	Anxiety, restlessness, insomnia (inability to sleep), confusion, psychotic states
Nervous system disorders	Headache, fainting, dizziness, tremor (an involuntary trembling or quivering), weakness
Cardiac disorders	Vasoconstriction hypertension, tachycardia (abnormally rapid heart rate), cardiac arrythmias (irregular heartbeat), anginal pain, palpitations (rapid or irregular heartbeat) and cardiac arrest.
Vascular disorders	Hypotension (abnormally low blood pressure) with dizziness, flushing
Respiratory, thoracic and mediastinal disorders	Dyspnoea (shortness of breath)
Gastrointestinal disorders	Gastro-intestinal disturbances, reduction of appetite, nausea, vomiting, diarrhoea, renal calcium oxalate calculi.
Skin and subcutaneous tissue disorders	Skin rash (erythematous or urticarial) and allergic reaction, mucosal lesions, sweating
Renal and urinary disorders	Micturition (discharge of urine), urinary retention.
General disorders and administrative site conditions	Fear, irritability, hypersalivation.

Not all side-effects reported for DEMAZIN FLU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice as soon as possible.

STORING AND DISPOSING OF DEMAZIN FLU

- Store all medicines out of the reach of children.
- Store at or below 25 ℃.
- Do not remove tablet from tube until immediately prior to use.
- Do not use after the expiry date on the carton.
- Return all unused medicine to your pharmacist.
- Protect from light or moisture.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF DEMAZIN FLU

DEMAZIN FLU is available as 10 Tablets packed in tubes.

IDENTIFICATION OF DEMAZIN FLU

Biplane orange-grey effervescent tablets.

REGISTRATION NUMBER

Y/5.8/308

NAME AND ADDRESS OF THE REGISTRATION HOLDER

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date on the registration certificate of the medicine: 12 May 2005

Date of the publication of this patient information leaflet: 25 March 1994