1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

ROBINUL 1 ml INJECTABLE

ROBINUL 2 ml INJECTABLE

Injection

Read all of this leaflet carefully before you are given ROBINUL INJECTABLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ROBINUL INJECTABLE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ROBINUL INJECTABLE CONTAINS

The active substance in: -

ROBINUL 1 ml INJECTABLE is glycopyrrolate 0,2 mg per 1 ml

ROBINUL 2 ml INJECTABLE is glycopyrrolate 0,4 mg per 2 ml

The other ingredients are chlorbutanol (preservative) 0,5 % *m/v* and water for injection.

WHAT ROBINUL INJECTABLE IS USED FOR

ROBINUL INJECTABLE stops the passage of certain nerve impulses involving acetylcholine.

ROBINUL INJECTABLE is used:

- Before an operation, to reduce saliva and other secretions and to make the stomach content less acidic.
- To protect against some of the unwanted effects of medicines such as neostigmine or pyridostigmine, which are used to reverse effects of certain types of muscle-relaxing medicines.

BEFORE ROBINUL INJECTABLE IS ADMINISTERED TO YOU

ROBINUL INJECTABLE should not be administered to you if you are hypersensitive (allergic) to glycopyrrolate or any of the other ingredients of ROBINUL INJECTABLE (see WHAT ROBINUL INJECTABLE CONTAINS).

Take special care with ROBINUL INJECTABLE

Tell your doctor or healthcare provider before being given the injection if:

- You are suffering from heart disease, heart failure, irregular heartbeat or high blood pressure;
- you have an overactive thyroid gland;
- you have a high temperature (fever);
- you have an enlarged prostate gland;
- you suffer from obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus);
- you suffer from glaucoma (increased pressure in the eye);
- you suffer from myasthenia gravis (leading to muscle weakness and fatigue);

- you have kidney problems or a kidney condition called uraemia.

Pregnancy and breastfeeding

The safety of ROBINUL INJECTABLE during pregnancy and whilst breastfeeding has not been established.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before receiving ROBINUL INJECTABLE.

Driving and using machinery

Since adverse reactions such as dizziness, mental confusion and blurred vision have been reported in patients receiving ROBINUL INJECTABLE, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that ROBINUL INJECTABLE does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Using other medicines with ROBINUL INJECTABLE

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

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

- Medicine for depression known as tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs).
- Clozapine which is used to treat severe mental disorders.
- Strong pain relievers such as nefopam.
- Amantadine which is used to treat Parkinson's disease or viral infection.

HOW TO USE ROBINUL INJECTABLE

You will not be expected to give yourself ROBINUL INJECTABLE. It will be given to you by a person qualified to do so.

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

If you receive more ROBINUL INJECTABLE than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

POSSIBLE SIDE EFFECTS

ROBINUL INJECTABLE can have side effects.

Not all side effects reported for ROBINUL INJECTABLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ROBINUL INJECTABLE, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching.

If you have such reactions, you may have had a serious allergic reaction to ROBINUL INJECTABLE. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- Increased or decreased heartbeat, irregular heartbeat;
- fainting.

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 reported less frequently:

- Mental confusion, nervousness, sleeplessness, headache, mental excitement (especially in the elderly), drowsiness, dizziness, giddiness;
- blurred vision, light sensitivity, a feeling of pressure in the eye;
- nausea (feeling sick), vomiting, constipation, bloated feeling, dry mouth, loss of taste;
- decreased sweating, flushing, dryness of the skin;
- difficulty in passing urine, impotence;
- suppression of lactation (breast milk becomes less);
- weakness.

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

STORING AND DISPOSING OF ROBINUL INJECTABLE

Store at or below 25˚C.

Protect from light.

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).

Store all medicines out of reach of children.

PRESENTATION OF ROBINUL INJECTABLE

ROBINUL 1 ml INJECTABLE is filled into a 1 ml clear glass ampoule with a break ring and is available in boxes of 10 and 100.–

ROBINUL 2 ml INJECTABLE is filled into a 2 ml clear glass ampoule with a break ring and is available in boxes of 10 and 100.–

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ROBINUL INJECTABLE

ROBINUL INJECTABLE is a clear, colourless liquid.

REGISTRATION NUMBER

ROBINUL1 ml INJECTABLE : J/5.4/50

ROBINUL 2 ml INJECTABLE : W/5.4/129

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

PHARMACARE LIMITED

Healthcare Park

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DATE OF PUBLICATION

Date of registration:

ROBINUL 1 ml INJECTABLE: 25 April 1977

ROBINUL 2 ml INJECTABLE: 16 August 1988

Date of the most recent amendment to the provider information as approved by the Authority:

09 April 2020

Botswana:	S2
ROBINUL 1 ml INJECTABLE:	BOT0500744
ROBINUL 2 ml INJECTABLE:	BOT0500743

Namibia:	NS1
ROBINUL 1 ml INJECTABLE:	04/5.4/0144
ROBINUL 2 ml INJECTABLE:	04/5.4/0143

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