1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

HY-PO-TONE 250

Film-coated tablet

HY-PO-TONE 500

Film-coated tablet

Read all of this leaflet carefully before you start taking HY-PO-TONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- HY-PO-TONE 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 HY-PO-TONE CONTAINS

The active substance is methyldopa anhydrous.

HY-PO-TONE 250:

Each film-coated tablet contains 250 mg methyldopa as anhydrous methyldopa.

The other ingredients are citric acid monohydrate, crospovidone, disodium edetate, iron

oxide yellow (C.I. 77492), magnesium stearate, methocel, microcrystalline cellulose, povidone, polyethylene glycol, quinoline yellow aluminium lake (C.I. 47005) and titanium dioxide (C.I. 77891).

Sugar free

HY-PO-TONE 500:

Each film-coated tablet contains 500 mg methyldopa as anhydrous methyldopa.

The other ingredients are citric acid anhydrous, crospovidone, disodium edetate, magnesium stearate, opadry II HP 58F22107 yellow, povidone and silicified microcrystalline cellulose.

Sugar free

WHAT HY-PO-TONE IS USED FOR

HY-PO-TONE belongs to a group of medicines called anti-hypertensives, which lower blood pressure. HY-PO-TONE tablets are used to treat high blood pressure (hypertension).

BEFORE YOU TAKE HY-PO-TONE

Do not take HY-PO-TONE and tell your doctor if you:

- Are allergic (hypersensitive) to methyldopa or any of the other ingredients.
- Have liver disease, or if your kidneys do not function properly.
- Have high blood pressure due to a tumour near the kidney (phaeochromocytoma).
- Suffer from depression.
- Suffer from porphyria.
- Are taking medicines for depression called monoamine oxidase inhibitors such as moclobemide or selegiline.

Take special care with HY-PO-TONE

Check with your doctor of pharmacist before taking HY-PO-TONE if you:

- Develop and unexplained fever.
- Are going to have a blood transfusion.
- Are going to have an operation in which you will be given anesthesia.
- HY-PO-TONE may cause darkening of the colour of your urine.
- Are taking other medicines such as imipramine, monoamine oxidase inhibitors (MAOI's) (see Taking other medicines with HY-PO-TONE).

Pregnancy and breastfeeding

The safety of HY-PO-TONE while pregnant and 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 taking HY-PO-TONE.

HY-PO-TONE is distributed into breast milk in small amounts.

Driving and using machinery

HY-PO-TONE may make you feel drowsy. Make sure you are not affected before you drive or operate machinery.

Taking other medicines with HY-PO-TONE

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription especially:

- Medicines used to treat high blood pressure,

- if you are taking lithium as lithium toxicity may occur,
- if you are using hepatotoxic medicines such as halothane; the combination is not advisable,
- medicines used to treat depression like tricyclic antidepressants as the blood pressure lowering effect may be diminished (see Take special care with HY-PO-TONE).

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

HOW TO TAKE HY-PO-TONE

Always take HY-PO-TONE exactly as your doctor 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:

Adults and children over 12 years:

HY-PO-TONE may be given as follows:

Initially 250 mg two or three times a day, for 2 days. Then increased every 2 or more days until an adequate response is achieved up to a maximum of 2 g daily.

If you have the impression that the effect of HY-PO-TONE is too strong or too weak, tell your doctor or pharmacist.

If you take more HY-PO-TONE than 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 HY-PO-TONE

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

POSSIBLE SIDE EFFECTS

HY-PO-TONE tablets can cause side effects. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

- Allergic reactions: inflammation of heart muscle or the sac surrounding the heart, skin rash which may be red and/or scaly, fever.
- HY-PO-TONE may alter the numbers and types of your blood cells and cause a rise in urea in the blood. If you notice increased bruising, nosebleeds, sore throat, infections or fever, you should tell your doctor who may want to give you a blood test.
- Drowsiness, headache, loss of strength or weakness, tingling or pins and needles, trembling and shuffling walk, partial paralysis of the face, involuntary jerky movements, mental changes including nightmares, confusion, depression, dizziness, lightheadedness, reduced blood flow to the brain.
- Slow heart rate and low blood pressure, worsening of existing heart pain, low blood pressure causing dizziness on standing, water retention causing swelling and weight gain.
- Blocked/stuffy nose.
- Feeling or being sick, bloated stomach, constipation, wind, diarrhoea, inflammation of the large bowel, mild dryness of the mouth, sore or “black” tongue, inflamed salivary glands and inflammation of the pancreas (pancreatitis). Tell your doctor immediately if you get very severe abdominal pains.
- Liver: abnormal liver function, hepatitis (inflammation of the liver), jaundice (yellowing of

the skin and/or whites of the eyes). These would be detected by a blood test.

- Skin: eczema (scaly and itchy rashes), hard skin rash (lichenoid), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis).
- Muscles and bones: joint pain with or without swelling. Muscle pain or cramps.
- Reproductive system and breasts: absence of menstrual periods, swelling of breasts in men and women, production of breast milk, failure to ejaculate, decreased sex drive, failure to maintain an erection (impotence).

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

STORING AND DISPOSING OF HY-PO-TONE

Store at or below 25 °C in a dry place.

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 HY-PO-TONE

HY-PO-TONE 250:

30 tablets are packed in a white polypropylene securitainer with or without a foam or rayon insert and sealed with a white low-density polyethylene securitainer cap.

100 tablets are packed in a white polypropylene securitainer with or without a foam or rayon insert and dessicant disc, which is sealed with white low-density polyethylene securitainer cap.

500 tablets are packed in a white polypropylene securitainer with or without a foam insert and silica gel sachet, which is sealed with a white low-density polyethylene securitainer cap.

28, 56 and 84 tablets are packed into metallised patient ready packs which are sealed with lay-flat zips after filling and packed into clear polyethylene bags.

1 000 tablets are packed into clear polyethylene bags, into 5 l tins.

HY-PO-TONE 500:
100 tablets are packed in a white polypropylene securitainer together with a desiccant and sealed with a white low-density polyethylene cap.

500 tablets are packed in a white polypropylene securitainer together with a silica gel sachet and foam insert and sealed with a white low-density polyethylene cap.

28 tablets are packed into metallised patient ready packs which are sealed with lay-flat zips and packed into polyethylene bags.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF HY-PO-TONE

HY-PO-TONE 250: A round, pale yellow, film-coated biconvex tablet bearing a distinctive H-

P-T logo on one side, free from cracking, peeling or chipping.

HY-PO-TONE 500: A pale yellow, round, biconvex film-coated tablet, free from cracking, peeling or chipping.

REGISTRATION NUMBER

HY-PO-TONE 250: K/7.1.3/90

HY-PO-TONE 500: K/7.1.3/209

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

DATE OF PUBLICATION

Dates of registration:

HY-PO-TONE 250: 09 December 1977

HY-PO-TONE 500: 05 December 1977

Date of the most recent amendment to the patient information leaflet as approved by the Authority: 01 March 2013

Botswana:	S2
HY-PO-TONE 250:	B9322375

HY-PO-TONE 500:	B9322380

Namibia:	NS2
HY-PO-TONE 250:	90/7.1.3/00982
HY-PO-TONE 500:	90/7.1.3/00983

Zimbabwe:	P.P.10
HY-PO-TONE 250:	92/12.3.3/2603

ZA_HYPOTAB_1303_02