PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml solution for injection.

Read all of this leaflet carefully before you start taking Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml** 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.

1. WHAT PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml CONTAINS:

The active substance is:

- Hyoscine butylbromide

The other ingredients are:

- Hydrobromic acid.
- Water for injection.

2. WHAT PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml IS USED FOR:

Hyoscine butylbromide works by relaxing the stomach, intestinal and bladder muscles.

Your doctor has therefore prescribed **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml** for you in order to treat any conditions associated with gastrointestinal spasm (cramps) that you may be suffering from.

3. BEFORE YOU RECEIVE PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml:

You should NOT be administered Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml if:

- You are allergic to hyoscine butylbromide or to any of the other ingredient of this injection (see **WHAT PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml CONTAINS**).
- You have a very fast heart rate
- If you suffer from a disturbance of your metabolism that can be seen as disorders of the skin or other organs.
- You suffer from muscle disorders causing weakness.
- You suffer from an enlarged prostate gland.
- You suffer from chronic diseases which affect your colon.
- You suffer from fever.
- You are pregnant or breastfeeding as the safety in pregnancy and lactation has not been established (see **Pregnancy and Breastfeeding**).

Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml if:

- You have any heart problems like fast heart rate, low blood pressure, heart disease or history of heart disease or high blood pressure.
- You suffer from conditions which are characterised by an increased heart rate such as thyroid toxicity, heart failure or if you are undergoing heart surgery as this medicine increase your heart rate.
- You have suffered from a heart attack, as this medicine may reduce supply of blood to the heart even more.
- You suffer from ulcers or sores of the colon.
- You suffer from diarrhoea.
- You suffer from increased pressure inside the eye called glaucoma.
- You are old and suffer from any impairment of your metabolic, liver or kidney function as you will be more prone to adverse effects like disorientation, delirium or sleepiness (see **Taking other medicines with Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**).
- Your child is taking this medication as they may be more susceptible to its adverse effects.
- Your doctor or healthcare professional may screen you before giving you this medicine and may also monitor you after giving you **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**.

- After being injected with **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**, you may experience a severe allergic reaction (anaphylaxis) or shock. As with all medicines causing such reactions, patients receiving this injection will be kept under observation.

Pregnancy and Breastfeeding:

You will not be given **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**:

- If you are pregnant or breastfeeding as the safety has not yet been established (see **You should NOT be administered Pharma-Q Hyoscine Butylbromide Injection 20 mg/1ml**).
- It may cross the placenta and harm your unborn baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before you receive **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**.

Driving and using machinery:

If you experience drowsiness you should not drive or operate machinery.

You should also avoid alcohol while you are on therapy with this medicine.

Taking other medicines with Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml may interact with other medicines:

- It will be used with care if you are concomitantly taking other medication which depress the central nervous system as depression may be enhanced (see **Special care should be taken with Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**).
- The effects of this medicine may be enhanced by medicines such as amantadine (medicine used to treat Parkinson’s disease), some antihistamines (medicines used for allergies), butyrophenones and phenothiazines (medicine used to treat mental disorders) and tricyclic antidepressants (medicine used to treat depression).

4. HOW TO RECEIVE PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml:

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

Always receive **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

The usual dose is:

For adults and children over 12 years of age:

- You will be given 20 mg directly into the muscle or directly into the vein, 2 to 3 times daily.
- Your dose will be repeated after 30 minutes, if necessary.
- Your maximum daily dose of 100 mg will not be exceeded.
- You will be observed for side-effects following administration by injection.

Children up to 6 years:

Your child will be given 10 mg directly into the muscle or directly into the vein, 2 to 3 times daily.

Infants and children up to 3 years:

Your infant or child will be given 5 mg directly into the muscle or directly into the vein, 2 to 3 times daily.

If you have the impression that the effect of **Pharma-Q Hyoscine**

Butylbromide Injection 20 mg/1 ml is too strong or too weak, talk to your doctor or pharmacist.

If you receive more Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml than you should:

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml overdose:

- You may suffer from increased heart rate, rapid breathing, drop in blood pressure when standing up quickly, fever, restlessness, confusion, excitement, loss of male sexual ability and false perceptions passing into delirium.

- You may get a rash which may appear on your face and upper body.
- If you are severely overdosed, you may suffer from depression of the central nervous system which may result in failure of your blood circulation and your breathing capabilities.
- You may also suffer from muscle paralysis with toxic doses.
- You will be injected repeatedly if necessary with a medicine called physostigmine.
- You will be given medical support and your symptoms treated.

In the event of an overdose, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

If you think that you did not receive a dose of **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**, contact your doctor.

If you have any further questions on the use of ***Pharma-Q Hyoscine Butylbromide Injection*** **20 mg/1 ml***, ask your doctor, nurse, or pharmacist.*

5. POSSIBLE SIDE EFFECTS:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml can have side effects.

Not all side effects reported for **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following serious side effects occur, stop receiving Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe allergic reactions (anaphylaxis) such as swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching.

These serious side effects and you may have had an allergic reaction to **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml.** You may need urgent medical care or hospitalisation.

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

- Decreased heart rate followed by increased heart rate, with palpitations and abnormal heart rhythms.

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

Tell your doctor as soon as possible if you notice any of the following:

Nervous system disorders:

Frequency unknown: Giddiness and staggering.

Eye disorders:

Frequency unknown: Increased dilation of the pupils of the eyes with loss of accommodation, increased sensitivity of the eyes to light and increased pressure inside the eye.

Cardio-Vascular disorders:

Frequent: **Tachycardia**

Frequency unknown: Decreased heart rate followed by increased heart rate, with palpitations and abnormal heart rhythms.

Gastro-intestinal disorders:

Frequency unknown: Dryness of the mouth, with difficulty in swallowing, thirst, reduction in the tone and motility of the gastro-intestinal tract, leading to constipation, vomiting and pain behind the breast-bone due to increased gastric reflux.

Skin and subcutaneous disorders:

Frequency unknown: Blushing, dryness of the skin, allergic reactions, including skin reactions.

Renal and urinary disorders:

Frequency unknown: Urinary urgency with the inability to do so.

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

6. STORING AND DISPOSING OF PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml:

Store at or below 25 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

7. PRESENTATION OF PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml:

Amber ampoules containing 20 mg/1 ml in containers of 10 or 100.

8. IDENTIFICATION OF PHARMA-Q HYOSCINE BUTYLBROMIDE INJECTION 20 mg/1 ml:

Clear, colourless solution in amber ampoules.

9. REGISTRATION NUMBER:

32/11.2/0242.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa.

11. DATE OF PUBLICATION:

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