#### PATIENT INFORMATION LEAFLET

#### HYOSCINE BUTYL BROMIDE INJECTION BP 10 MG/ML

Hyoscine Butyl Bromide BP

## Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

#### In this leaflet:

- a) What Hyoscine Butyl Bromide Injection BP 10 mg/ml is and what it is used for
- b) Before you take use Hyoscine Butyl Bromide Injection BP 10 mg/ml
- c) How to take use Hyoscine Butyl Bromide Injection BP 10 mg/ml
- d) Possible side effects
- e) How to store Hyoscine Butyl Bromide Injection BP 10 mg/ml
- f) Further information

# WHAT HYOSCINE BUTYL BROMIDE INJECTION BP 10 MG/ML IS AND WHAT IT IS USED FOR

Hyoscine Butyl Bromide Injection BP 10 mg/ml contain a medicine called 'hyoscine butylbromide'. This belongs to a group of medicines called 'antispasmodics'.

Hyoscine Butyl Bromide Injection BP 10 mg/ml are used to relieve cramps in the muscles of your:

- Stomach
- Gut (intestine)
- Bladder and the tubes leading to the outside of your body (urinary system)

Hyoscine Butyl Bromide Injection BP 10 mg/ml can also be used in some diagnostic and therapeutic medical procedures where spasm may be a problem for example barium enema.

#### Do not take Hyoscine Butyl Bromide Injection BP 10 mg/ml

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients.
- You have glaucoma (an eye problem)

- You have megacolon (a very enlarged bowel)
- You have something called 'myasthenia gravis' (a very rare muscle weakness problem)
- You have a very fast heart rate
- You have difficulty or pain passing water (urine) such as men with prostate problems
- You have gut blockage problems or a totally inactive gut
- You are pregnant, likely to get pregnant or are breast-feeding

You should not receive this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

#### Take special care with Hyoscine Butyl Bromide Injection BP 10 mg/ml

- You have any heart problems.
- You have a fever.
- You have problems with your thyroid gland such as an overactive thyroid gland.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before receiving Hyoscine Butyl Bromide Injection BP 10 mg/ml.

Check with your doctor or pharmacist straight away if you have unexplained abdominal pain which persists or worsens or occurs with:

- fever
- feeling sick
- being sick
- changes in your bowel movements
- abdominal tenderness
- low blood pressure
- feeling faint or,
- blood in your bowel movements

## **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Hyoscine Butyl Bromide Injection BP 10 mg/ml can affect the way some other medicines work. Also some other medicines can affect the way Hyoscine Butyl Bromide Injection BP 10 mg/ml work.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Medicines for depression called 'tetracyclic antidepressants' or 'tricyclic antidepressants' such as doxepin
- Medicines for allergies and travel sickness called 'antihistamines'
- Medicines to control your heart beat such as quinidine or disopyramide
- Medicines for severe mental illness such as haloperidol or fluphenazine
- Medicines usually used for breathing problems such as salbutamol, ipratropium, tiotropium or atropine-like medicines
- Amantadine for Parkinson's disease and flu

• Metoclopramide - for feeling sick (nausea)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before receiving Hyoscine Butyl Bromide Injection BP 10 mg/ml.

#### Taking Hyoscine Butyl Bromide Injection BP 10 mg/ml with food and drink

You can take hyoscine tablets with or without food.

# **Pregnancy and breast-feeding**

You should not be given Butyl Bromide Injection BP 10 mg/ml if you are pregnant, likely to get pregnant or are breast-feeding.

# **Driving and using machines**

Some people may have sight problems or feel dizzy while taking this medicine. If this happens to you, wait until your sight returns to normal or you stop feeling dizzy before driving or using any tools or machines.

# Important information about some of the ingredients of Butyl Bromide Injection BP 10 mg/ml

Hyoscine Butyl Bromide Injection BP 10 mg/ml contain sodium chloride. The amount of sodium in a 1 ml ampoule is less than 1 mmol (23 mg), the total amount of sodium if you are given five ampoules in 24 hours is less than 1 mmol (23 mg) this means that your medicine is essentially sodium free.

#### a) HOW TO TAKE HYOSCINE BUTYL BROMIDE INJECTION BP 10 MG/ML

Hyoscine Butyl Bromide Injection BP 10 mg/ml are usually given by a doctor or nurse. Hyoscine Butyl Bromide Injection BP 10 mg/ml should not be given every day for long periods of time.

Receiving the injection

Hyoscine Butyl Bromide Injection BP 10 mg/ml may be given in two ways:

- By being slowly injected into a vein
- By an injection into a muscle
- Hyoscine Butyl Bromide Injection BP 10 mg/ml may be diluted with other solutions if needed

How much will you be given

You will usually be given one ampoule, but you may be given a further ampoule after half an hour if required

If you are being given Hyoscine Butyl Bromide Injection BP 10 mg/ml as part of an endoscopy your dose may need to be given more often

You should not be given more than 5 ampoules in any 24-hour period

Hyoscine Butyl Bromide Injection BP 10 mg/ml are not recommended for children.

## If you take more Hyoscine Butyl Bromide Injection BP 10 mg/ml than you should

It is unlikely that you will be given too much of this medicine. However, tell the doctor or nurse if you think that you have been given too much.

#### If you forget to take use Hyoscine Butyl Bromide Injection BP 10 mg/ml

If you forget your dose, take it as soon as you remember. But, if it is nearly time for your next dose, just take the next dose at the right time. Do not take double the dose.

# If you stop taking Hyoscine Butyl Bromide Injection BP 10 mg/ml

Ask your doctor, health care provider or pharmacist if the course in completed

## b) POSSIBLE SIDE EFFECTS

Like all medicines, Hyoscine Butyl Bromide Injection BP 10 mg/ml can cause side effects although not everybody gets them. The following side effects may happen with this medicine.

Stop taking your medicine and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- Allergic reactions such as skin rash, nettle rash, redness of the skin and itching
- Severe allergic reactions (anaphylaxis) such as difficulty breathing, feeling faint or dizzy (shock)
- Painful red eye with loss of vision

#### Other side effects

- Dry mouth (affects fewer than 1 in 10 people)
- Dizziness (affects fewer than 1 in 10 people)
- Blurred vision (affects fewer than 1 in 10 people)
- Increased heart rate (affects fewer than 1 in 10 people)
- Constipation
- Abnormal sweating or reduced sweating
- Being unable to pass water (urine)
- Low blood pressure, for example feeling faint
- Flushing
- Dilated pupils
- Increased fluid pressure inside the eye

Pain at the place you had the injection may occur if you have been given Hyoscine Butyl Bromide Injection BP 10 mg/ml

Although unlikely, in certain circumstances it may be possible that Hyoscine Butyl bromide Injection BP 10 mg/ml may pass into the brain and cause side effects, for example confusion.

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible

side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

## **United Kingdom**

Yellow Card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### HOW TO STORE MORE HYOSCINE BUTYL BROMIDE INJECTION BP 10 MG/ML

Keep out of the reach and sight of children

Store below 30°C, keep the ampoules in the outer carton in order to protect from light. Hyoscine butyl bromide injection BP 10 mg/ml should not be used after the expiry date which is printed on the carton and ampoules. The expiry date refers to the last day of that month

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

## c) FURTHER INFORMATION

# What more Hyoscine Butyl Bromide Injection BP 10 mg/ml contains

Each ampoule contains 10 mg of the active ingredient hyoscine butylbromide. The other ingredients are sodium chloride. Sodium Hydroxide and water for injections.

## What Hyoscine Butyl Bromide Injection BP 10 mg/ml looks like and contents of the pack

Hyoscine Butyl Bromide Injection BP 10 mg/ml are clear glass ampoules with coloured identification rings, containing a colourless or almost colourless, clear solution.

Hyoscine Butyl Bromide injection BP 10 mg/ml are supplied in cartons containing 10 x 1 ml ampoules.

## Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Ciron Drugs & Pharmaceuticals Pvt. Ltd.

C-1101 / 1102, Lotus Corporate Park, Graham Firth Steel Compound,

Jay Coach Junction, Western Express Highway,

Goregaon (East), Mumbai -400 063. INDIA

Phone: +91-22-62748000

E Mail: mail@cironpharma.com Website: www.cironpharma.com

For any information about this medicinal product, please contact the local representative of the>supplier:

RWANDA {Country}

Rene Pharmacy {Name}

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