# **BENNASTON SYRUP (Alcohol Free)**

Methadone hydrochloride (5mg/ml)

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# What Bennaston Syrup (Alcohol Free) is used for

Bennaston Syrup (Alcohol Free) is used for treatment of addiction to opioid drugs.

# How Bennaston Syrup (Alcohol Free) works

Bennaston Syrup (Alcohol Free)contains Methadone hydrochloride as active ingredient.

Methadone hydrochloride belongs to a group of medicines called opioid analgesics.

Ask your pharmacist or doctor if you have any questions about this medicine.

# Before you use Bennaston Syrup (Alcohol Free)

#### -When you must not use it

Do not take Bennaston Syrup (Alcohol Free) if:

- You are allergic to Methadone hydrochloride, any other opioid drug, or to any of the ingredients listed at the end of this leaflet.
- You have any other medical condition including:

- Suffering from respiratory depression (difficulty in breathing), especially if there is excessive phlegm or skin is bluish in colour or a lung disorder such as asthma
- Alcoholism
- A recent head injury or increased pressure in the head
- You are taking or have resently taken (within 14 days) antidepressants called monoamine oxidase inhibitors (MAOIs)
- A bowel condition known as ulcerative colitis
- Liver problems
- You suffer from biliary and renal tract spasm
- Certain heart conditions

### -Before you start to use it

Tell your doctor if you have or have had any of the following medical conditions:

- Phenylketonurics (disorder that causes an amino acid build up in your body).
- Heart, respiratory, kidney or liver problems.
- hormone problems
- thyroid gland or pituitary gland problems
- diabetes
- prostate disease
- shock
- with prolonged used, your body will become used to taking this medicine and you may experince symptoms due to withdrawal if you suddenly stop taking it, thus, discontinuation of therapy should be carried out gradually.

## Pregnancy and breast feeding:

Please consult your doctor before start to use Bennaston Syrup (Alcohol Free) if you are pregnant, plan to become pregnant, breastfeeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Bennaston Syrup (Alcohol Free) against the benefits they expect it will have for you.

#### -Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

- rifampicin, an antibiotic
- phenytoin, a medicine for fit
- carbamazepine, a medicine for fit
- St John's wort
- Nevirapine, efavirenz and protease inhibitors, medicines to treat HIV infections
- fluconazole, an antifungal
- Fluvoxamine, selective serotonin re-uptake inhibitors (SSRIs) which are medicines to treat depression
- antiarrhythmics, medicines for heart
- neuroleptics medicine, a psychiatric medicines
- tricyclic antidepressants, medicines for depression
- calcium channel blocker, medicines for high blood pressure.
- diuretics, 'water pills'.
- laxatives
- mineralocorticoid hormones, a medicine used in certain hormone conditions
- monoamine oxidase inhibitors (MAOIs), medicines to treat depression.
- Medications that acting on the central nervous system, such as barbiturates, muscle

relaxants, phenothiazines, tranquilisers and some psychotropic medicines.

• Narcotic antagonist

# How to use Bennaston Syrup (Alcohol Free)

#### -How much to us

A single dose of 10 to 20mg by mouth can be given initially and increased as necessary by 5 to 10mg daily. The dose must not be increased by more than 5 to 10mg daily and by not more than 30mg in any 7 day period. After stabilization, which can often be achieved with a dose of 30 to 50mg daily (up to maximum of 80mg daily), the dose of methadone is gradually decreased until total withdrawal is achieved. Some treatment schedule for opioid dependence involved prolonged maintenance therapy with methadone where the daily dose is adjusted carefully for the individual.

For oral administration only.

Methadone is not suitable for children.

### -When to use it

Take this medicine as per advised from the doctor.

### -How long to use it

Do not stop taking Bennaston Syrup (Alcohol Free)or change the dose without first checking with your doctor.

### -If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time.

Do not try to make up for missed doses by taking more than one dose at a time.

#### -If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Bennaston Syrup (Alcohol Free) The signs and symptoms of overdose as below:

- · respiratory depression
- pin-point pupils
- hypotension (low blood pressure)
- circulatory failure
- pulmonary oedema (fluid accumulation in the lung)
- coma
- dealth
- mydriasis (dilatation of the pupil)
- asphyxia (lack of oxygen)
- drowsiness
- floppiness
- apnoea (breathing problem)

### While you are using it

## -Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Bennaston Syrup (Alcohol Free)

## -Things you must not do

Do not drink alcohol when you are taking Bennaston Syrup (Alcohol Free).

## -Things to be careful of

Bennaston Syrup (Alcohol Free) may cause drowsiness and orthostatic hypotension (low blood pressure due to changing of posture).

It is recommended that you do not drive, use machinery or undertake any activities where alertness is required.

Particular care should be taken when starting on treatment with Bennaston Syrup (Alcohol Free) or increasing the dose. Bennaston Syrup (Alcohol Free) can decrease heart and breathing rates, which if severe may lead to death.

#### Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Bennaston Syrup (Alcohol Free). Bennaston Syrup (Alcohol Free) helps most people who take it but it may have unwanted side effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor if you notice any of the following:

Common side effects:

- nausea and vomiting
- · drowsiness or dizziness
- sweating
- respiratory depression
- circulatory depression
- · respiratory arrest
- shock
- cardiac arrest.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

## Storage and Disposal of Bennaston Syrup (Alcohol Free)

#### -Storage

Store below 30°C. Keep in a cool dry place, protected from strong light. Keep out of reach of children.

## -Disposal

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 to protect the environment.

## **Product description**

#### -What it looks like

Bennaston Syrup (Alcohol Free) is a clear red liquid (alcohol free).

## -Ingredients

Active ingredients: Each ml contains 5mg of methadone hydrochloride

Inactive ingredients:
Sodium Benzoate, Citric Acid,
Ponceau 4R, Polyethylene glycol,
Sodium Saccharin, Glycerin,
Sodium Citrate and Water.

MAL number: MAL08111933AZ

#### Manufacturer:

HOE Pharmaceuticals Sdn Bhd Lot 10, Jalan Sultan Mohamed 6, Bandar Baru Suleiman, 42000 Port Klang, Selangor, MALAYSIA.

# **Product Registration Holder:**

HOE Pharmaceuticals Sdn Bhd Lot 10, Jalan Sultan Mohamed 6, Bandar Baru Suleiman, 42000 Port Klang, Selangor, Malaysia.

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21/10/2015

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