

**PATIENT INFORMATION LEAFLET**

**TEFECHOLINE® (BETHANECHOL CHLORIDE TABLETS 25 mg USP)**

Read all of this leaflet carefully before you start using 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 or pharmacist.

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**1. WHAT TEFECHOLINE IS AND WHAT IT IS USED FOR**

TEFECHOLINE belong to a group of medicines called choline esters.

The active ingredient in TEFECHOLINE is bethanechol chloride. They are used to treat urinary retention (holding urine in the bladder) following, for example, an operation or after giving birth, and also in the treatment of reflux oesophagitis (inflammation of the oesophagus).

**2. BEFORE YOU TAKE TEFECHOLINE**

**Talk to your doctor or pharmacist**

TEFECHOLINE are not recommended for children.

Do not take TEFECHOLINE if you:

- Are allergic (hypersensitive) to bethanechol chloride or to any of

the other ingredients in TEFECHOLINE (See section 6. Further information)

- have had a blockage of your gut
- have had problems passing water due to a blockage
- have had recent heart attack
- have had recent surgery on your stomach
- are pregnant or breast feeding
- are elderly (over 70 years of age).

If any of the above points apply to you, speak to your doctor or pharmacist before taking TEFECHOLINE.

**Using other medicines**

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

Please check with your doctor if you are taking any of the following before taking TEFECHOLINE:

- medicines used to treat abnormal heart rhythms (e.g. quinidine and procainamide)
- other medicines used to treat urinary retention (e.g. distigmine and carbachol)
- medicines that are used to reduce high blood pressure in emergency situations (e.g. trimethaphan).

**Taking TEFECHOLINE with food and drink**

It is advisable to take TEFECHOLINE on an empty stomach to reduce the risk of feeling sick. They should be taken half an hour before food.

**Pregnancy and breast feeding**

Do not take TEFECHOLINE if you are pregnant, think you are pregnant or are trying to become pregnant.

Do not take TEFECHOLINE if you are breast feeding.

### **Driving and using machines**

Occasionally Bethanechol chloride may interfere with an individual's ability to drive or operate machinery. If affected, you should not drive or operate machinery.

### **3. HOW TO TAKE TEFECHOLINE**

Always take TEFECHOLINE exactly as your doctor has told you.

Ask your doctor or pharmacist if you are not sure.

- The usual dose for adults is 10 to 25 mg taken three to four times a day.
- TEFECHOLINE should be swallowed whole with a glass of water. They should be taken half an hour before food.
- It is advisable to take TEFECHOLINE on an empty stomach to reduce the risk of feeling sick.
- TEFECHOLINE are not recommended for children or the elderly.

### **If you take more TEFECHOLINE than you should**

If you take too many tablets, or somebody else accidentally swallows your tablets, contact your doctor or the nearest hospital casualty department immediately.

### **If you forget to take TEFECHOLINE**

If you miss a dose and remember within an hour of when you should have taken it, you can take your usual dose.

If, however, you forget and remember after two or more hours, do not take it but wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

### **4. POSSIBLE SIDE –EFFECTS**

Like all medicines TEFECHOLINE can cause side effects, although not everybody gets them.

Possible side effects include feeling and being sick, sweating and stomach pains/ spasms.

#### **General condition:**

Very common: increased salivation and sweating

Common: decreased body temperature (hypothermia)

Very rare: chest pain, heat sensation, feeling tense, headache

#### **Cardio-vascular system**

Common: slowed down pulse rate below 60 beats per minute (bradycardia), drop in blood pressure

Rare: especially at the beginning of therapy sudden changes of posture may lead to feeling of dizziness or giddiness (orthostatic hypotension)

#### **Digestive tract:**

Common: diarrhoea

Uncommon: nausea and vomiting, gastrointestinal disturbances

Very rare: eructation, gastric or intestinal ulcer

Urinary system:

Very common: urinary urgency

#### **Eyes:**

Very rare: increased lachrymation, blurred vision, changes in accommodation ability

#### **Respiratory tract:**

Very rare: especially in patients with respiratory problems: bronchospasm, hampered breathing, wheezing

#### **Skin:**

Very common: skin flushing

Very rare: rash (Miliaria cristallina)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE TEFECHOLINE**

### **Keep out of the reach and sight of children**

Do not use TEFECHOLINE after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Store in the original packaging

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

## **6. FURTHER INFORMATION**

### **What TEFECHOLINE contain**

The active ingredient in Tablets is bethanechol chloride. Each tablet contains 25 mg of the active ingredient.

The other ingredients are calcium sulphate dihydrate BP, maize starch BP and talc BP (iron free).

### **What TEFECHOLINE look like and the contents of the pack**

TEFECHOLINE are white in colour with a cross score line across the tablet and the embossment.

Each pack contains 100 tablets

Available in blister packs

Strength of 10 mg is also available

### **Manufactured By:**

TAJ PHARMACEUTICALS Ltd.  
Mumbai, INDIA

### **Marketed By:**

TAJ PHARMA INDIA LTD.  
CRESCENT, SAHAR AIRPORT ROAD,  
MUMBAI, MAHARASHTRA 400059  
INDIA

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