

Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription; however you will still need to use this medicine carefully to get the best from it.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Not to be used for more than 5 days in children without the advice of a doctor. Parents or carers should seek medical attention if the child's condition worsens during treatment.
- This medicine can lead to dependence. Therefore the treatment should be of short duration.

What is in this leaflet:

1. What Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution is and what it is used for
2. What you need to know before you take Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution
3. How to take Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution
4. Possible side effects
5. How to store Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution
6. Further Information

1. What Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution is and what it is used for

The active ingredient Dextromethorphan belongs to a group of medicines called cough suppressants that work by providing relief from dry painful coughs.

2. What you need to know before you take Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution.

Do not use:

- If you are allergic to Dextromethorphan, Propylene Glycol or any other ingredients
- If you have liver disease or if you are at risk of respiratory failure
- If you are taking selective serotonin reuptake inhibitors.

Talk to your pharmacist before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

Important information:

- The use of Dextromethorphan with alcohol or sedatives may increase the effects on the body and can cause poisoning in small doses.
- Caution is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.
- To be taken into account in patients with epilepsy.

Not to be used in patients taking medications for depression, psychiatric or emotional conditions, Parkinson's disease, monoamine inhibitors or within 14 days of stopping treatment.

Ask your doctor before use if suffering from a chronic or persistent cough, if you have asthma, suffering from acute asthma attack or where the cough is accompanied by excessive secretions.

Do not take with any other cough and cold medicine.

Pregnancy and breast-feeding

Consult your doctor or pharmacist before using this product if you are pregnant, breast-feeding or if you are taking any prescribed medicines.

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you
- It may be an offence to drive when taking this medicine
- However, you would not be committing an offence if:
 - The medicine has been taken to treat a medical problem and
 - You have taken it according to the information provided with the medicine and
 - It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Taking other medicines

Consult your doctor or pharmacist if you are taking any prescribed medications, the following in particular (or similar) should be borne in mind:

- Quinidine or Amiodarone or any other medicines which are used to treat heart conditions
- Fluoxetine, Paroxetine and Terbinafine
- Flecainide and Propafenone
- Sertraline and Bupropion
- Methadone used for severe pain

- Cinacalcet used to treat an overactive parathyroid gland
- Haloperidol, Perphenazine and Thioridazine

If you are taking medicines such as certain antidepressants or antipsychotics Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).

Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml contains the following:

- E420 (Sorbitol) – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicinal product.
- 3.6 g of Glucose per 10 ml dose. This should be taken into account in patients with diabetes mellitus.
- E124 (Ponceau R Red) – may cause allergic reactions.

3. How to take Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution

Liquid for oral use.

Adults and children over 12 years: Take two 5 ml spoonfuls (10 ml) up to four times daily.

Children from 6-12 years: Take one 5 ml spoonful up to four times daily.

Not to be used for more than 5 days without the advice of a doctor.

Medical attention should be sought if the child's condition deteriorates during treatment.

Not recommended for use in children under 6 years. Do not take more medicine than the label tells you to. Avoid alcoholic drink.

If you take more Bell's Dual Action Dry Cough 10 mg per 5 ml Oral Solution than you should, you may experience the following symptoms:

nausea, sickness, dizziness, slurred speech, muscle contraction, rapid eye movement, drowsiness, tremor, difficulty breathing, mental stimulation such as excitation, confusion and psychosis. Serious adverse events may occur in children in case of overdose including neurological disorders. Caregivers should not exceed the recommended dose.

Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions. Contact your doctor or hospital straight away if you experience any of the above symptoms.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

If you get any of these serious side effects, stop taking the medicine immediately and consult your doctor or pharmacist:

- Allergic reactions including swelling of the face or difficulty breathing
- Feeling sick, being sick or stomach discomfort
- Dizziness, drowsiness or confusion
- Skin rashes
- Convulsions.

Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised
 - You feel you need to use more than the recommended dose
 - You are using the medicine for reasons other than those indicated
 - When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again
- If you notice any of these signs, it is important you talk to your doctor or pharmacist.

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 via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bell's Healthcare Dual Action Dry Cough 10 mg per 5 ml Oral Solution

Keep out of the sight and reach of children.

Do not store above 25°C.
Store in the original container.

6. Further information

What Bell's Dual Action Dry Cough 10 mg per 5 ml Oral Solution contains:

Each 5 ml contains 10 mg of the active substance Dextromethorphan Hydrobromide.

Active Ingredient: Dextromethorphan Hydrobromide 10 mg per 5 ml.

Other Ingredients: Glucose, Propylene Glycol, E420 (Sorbitol), Menthol, Orange Flavouring, E124 (Ponceau R Red), E954 (Saccharin Sodium), E330 (Citric Acid) and Purified Water.

Bell's Dual Action Dry Cough 10 mg per 5 ml Oral Solution is a liquid supplied in a 200 ml bottle.

Manufacturer and Product Licence Holder:

Bell, Sons & Co. (Druggists) Ltd.,
Gifford House, Slaidburn Crescent, Southport,
PR9 9AL, UK.

Product Licence Number:

PL 03105/0076

This leaflet was last revised April 2020
C73-0430 Version A