Patient Information Leaflet

BETAISODONA® Throat Spray

MUNDIPHARMA
Pharmaceuticals Ltd.

Please read this leaflet carefully, it contains important information.
For further information, consult your doctor or pharmacist.
Keep this leaflet in a safe place – you may want to read it again.

Product name: BETAISODONA® Throat Spray

Composition:
***Active Ingredients*:** Povidone-Iodine 0.45% w/v.
***Excipients*:** Glycerol, Menthol, Eucalyptus Oil, Ethanol, Potassium Iodide, Purified Water.

Pharmaceutical Form: Throat Spray Solution

Description: BETAISODONA® Throat Spray is an oral solution. It is a smooth yellowish-brown liquid, supplied in yellowish polyethylene container with a white spray valve and a styrene transparent cap. The content of the product is 50ml and is enclosed in printed carton.

Pharmaceutical Group: Antiseptic

Manufactured by: MUNDIPHARMA PHARMACEUTICALS LTD.

Under license from: MUNDIPHARMA AG, Basle/Switzerland.

Marketing/Product Authorization Holder:
MUNDIPHARMA PHARMACEUTICALS LTD.
13 Othellos str. Dhali Industrial Zone, P.O.Box 23661,
1685 Nicosia, Cyprus, Tel: 22815656, Fax: 22487133

WHAT YOU NEED TO KNOW ABOUT THIS MEDICATION

1. Therapeutic Indications:
*Why use **BETAISODONA® Throat Spray**?*
- **BETAISODONA® Throat Spray** is indicated for the treatment of acute mucosal infections of the mouth and pharynx including stomatitis, gingivitis, aphthous ulcers, pharyngitis, tonsillitis, monilial infections, common colds and influenza.
- For oral hygiene prior to, during and after surgery dental and oral surgery.

2. Contraindications
*When should you not use **BETAISODONA® Throat Spray**?*
- Do not use in patients hypersensitive to iodine or any other of the ingredients listed at the beginning of this leaflet.
- Do not use in patients with thyroid disorders (in particular nodular colloid goiter, endemic goiter and Hashimoto's thyroiditis).
- Do not use in patients taking lithium.
- Do not use in children under 6 years of age.

3. Precautions for use:
What precautions have to be taken during the use of the product?
- Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency.
- Thyroid function tests may be affected using products containing iodine.
- Povidone-Iodine should not cover for a long period large areas of the skin (e.g. not more than 10% of the total body surface and not for longer than 14 days) unless strictly indicated. Even after the end of the treatment (up to 3 months) one should look for the early symptoms of possible hyperthyroidism and if necessary the thyroid function should be monitored.
- Contamination with Povidone-Iodine of several tests for detecting occult blood in faeces or blood in urine may produce false-positive results.
- During pregnancy and lactation **BETAISODONA® Throat Spray** should only be used under medical prescription.
- Effects on the ability to drive and use machinery:
No such influence has been reported.

4. Interactions:
*Can using the **BETAISODONA® Throat Spray** influence the effects of other treatments*?
- The concomitant use of products containing enzymatic component, hydrogen peroxide, silver and taurolidine lead to a weakening effect of both substances.
- Simultaneous use with mercury products may lead to the formation of a substance, which can damage the mucosa.
- Using this treatment may interfere with tests or thyroid function and can make a planned treatment of the thyroid with iodine impossible. After the end of the treatment an interval of at least 1-2 weeks should be allowed before a new scintigram is carried out.
- Several types of tests for detecting occur (not visible) blood in faeces or blood in urine may be affected (i.e. produce false-positive results).

5. Instructions for use:
*How to use **BETAISODONA® Throat Spray**?*

Adults, Elderly and Children over 6 years of age: Topical use.

- Spray to the mucous membrane of the throat several times a day (every 3-4 hours) or as directed by your doctor or dentist.
- If you forget to use your medication, use it as soon as you remember unless it's time for the next application. Then follow the original instructions for use.
- The duration of treatment is decided by your doctor according to the indications of your problem.

6. Overdose. Clinical Symptoms. Therapy.
*What to do in the event of accidental ingestion of **BETAISODONA® Throat Spray**?*
In the event of accidental or deliberate ingestion of large quantities of **BETAISODONA® Throat Spray,** contact immediately your doctor or nearest hospital.
Overdose can cause symptoms like metallic taste in the mouth, increased salivation, burning or pain in the throat or mouth, irritation and swelling in the eyes, breathing difficulties due to pulmonary oedema, skin reactions, gastrointestinal upset and diarrhoea. Metabolic acidosis, hypernatraemia and renal impairment may occur.

Therapy: Symptomatic and supportive treatment should be provided, with special attention to electrolyte balance and renal and thyroid function.

7. Side Effects:
What undesirable effects might this treatment cause?
Povidone-Iodine may produce local skin reactions although it is less irritant than iodine. It may also produce mucous irritation of the mouth as well as hypersensitivity reactions. Should you experience any of the above side effects or any other unusual effects, stop using the medicine and consult your doctor or pharmacist at once.
The application of povidone iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypenatriaemia and impairment of renal function. In single cases acute generalised allergic reaction with drop in blood pressure and/or shortness of breath (anaphylactic reactions) have been reported.

8. Storage Precautions:
*How to store **BETAISODONA® Throat Spray**?*
- Store this product at or below 25°C, in the packaging that it comes in.
- Do not use this product after the expiry date shown on the pack.
- KEEP OUT OF THE REACH OF CHILDREN

9. Other information:
Date leaflet prepared: September 2003
Date leaflet Reviewed: April 2006

®: BETAISODONA is a Registered Trade Mark.

10204904

Digitally signed by Thekla M. Petrou
DN: cn=Thekla M. Petrou, o=Mundipharma Pharmaceuticals Ltd, ou, email=Thekla.M.Petrou@mundipharma.com.cy, c=CY
Date: 2011.11.29 15:03:44 +02'00'