SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Utabon Adults

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Oxymetazoline hydrochloride: 0.5 mg/ml.
Excipients: see section 6.1

3. PHARMACEUTICAL FORM
Nasal spray, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Local relief of the symptoms of nasal congestion in patients suffering from colds, allergic rhinitis and other nasal disorders such as sinusitis.

4.2 Posology and method of administration
Nasal use.
Adults and children older than 12 years: one spray into each nostril, maximum twice a day.

After each use, clean the tip of the nozzle with a clean, moist cloth before closing the flask.

4.3 Contraindications
Utabon is contraindicated in patients with a history of hypersensitivity to oxymetazoline or other decongestive adrenergic substances or any of the components of this medicinal product.

4.4 Special warnings and special precautions for use
Do not use during periods longer than three days without medical prescription. This medicinal product should be used with caution if the patient suffers from diabetes mellitus, arterial hypertension, cardiovascular diseases, glaucoma, prostatic hypertrophy, hyperthyroidism or is taking adrenergic antidepressants or bronchodilators, phenothiazines or methyldopa.

In rare occasions, this medicinal product may increase the symptoms of nasal congestion instead of reducing them. This is because the effects of oxymetazoline are temporary and prolonged use may produce a rebound effect causing vasodilation, congestion and rhinitis.

Rarely, this product may cause insomnia. In this case this medicinal product should not be administered late in the evening or at night.

Use in children: This strength should not be used in children under the age of 12.

Children may be particularly liable to systemic absorption of oxymetazoline and to its adverse effects.

The use of the same nasal spray flask by more than one person can be a source of infection.

Warning about excipients:
This medicinal product contains benzalkonium chloride, that may cause bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

This medicinal product should not be administered together with monoaminoxidase inhibitors (MAOI), adrenergic bronchodilators, tricyclic antidepressants, phenothiazines, methyldopa and antiasthmatic products.

4.6 Pregnancy and lactation

It is not advisable to use this medicinal product during pregnancy or lactation because oxymetazoline may be absorbed systemically. Therefore, if necessary, the benefits and/or risks involved should be assessed.

4.7 Effects on ability to drive and use machines

Although this kind of effects are not expected, if the patient undergoes drowsiness or dizziness driving is not recommended.

4.8 Undesirable effects

This product may cause the following undesirable effects:

Common (> 1/100, < 1/10): sneezing and irritation, dryness, or itching of the nasal mucosa. Excessive or prolonged use may result in rebound congestion.

Rare (> 1/10000, < 1/1000): Excessive administration of this product may produce the following symptoms: headache, shivering, sleep disorders, excessive sweating, palpitations, nervousness.

Treatment should be discontinued If undesirable effects appears and it must be notified to the pharmacovigilance systems.

4.9 Overdose

The administration of excessive doses, very continued doses or accidental ingestion can lead to systemic absorption causing headache, shivering, sleep disorders, excessive sweating, palpitations and nervousness.

In case of overdose (mean lethal dose in children under 2 years of age, 10 mg; in adults at least 10 times more) the stomach should be emptied by emesis or gastric lavage followed by repeated doses of activated charcoal (every 4-6 hours) plus a saline laxative.

Blood pressure, pulse, convulsions and excitement shall be monitored, as well as the sympathomimetic effects.

Vasopressor drugs are contraindicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics for nasal administration.
ATC Code: R01AA05.

Oxymetazoline is an imidazole derivative, similar in structure to adrenergic drugs, with specific action on the α_1 adrenergic receptors that causes local vasoconstriction and, therefore, reduces nasal congestion.

5.2 Pharmacokinetic properties

When oxymetazoline is administered topically on the nasal mucosa, the onset of action is very fast (5 to 10 minutes) and lasts several hours (8 to 12 hours).

Available literature states up to 50% reduction in nasal blood flow after topical administration of doses between 10 and 120 μg of oxymetazoline. This reduction has been shown to be significant 5 minutes after administration by this route.

Oxymetazoline can be absorbed systemically through the nasal mucosa and the gastrointestinal tract, causing systemic side effects, particularly when excessive doses are given. Children and the elderly are more liable to absorb this drug.

The elimination half-life is approximately 5 to 8 hours.

In the first 72 hours, 30% of the absorbed drug is excreted unchanged through the urine and approximately 10% through the faeces.

5.3 Preclinical safety data

Given its extensive clinical use, safety problems are not expected when this medicinal product is used at the recommended doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride,
disodium phosphate anhydrous,
sodium dihydrogen phosphate dihydrate,
glycine,
sorbitol,
purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Maintain below 25°C.

6.5 Nature and contents of container

Sprayer flask.
Each flask contains 15 ml of nasal spray solution.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

MA131/00501

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th July 2007

10. DATE OF REVISION OF THE TEXT