Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Anomex Plus Suppositories

2. Qualitative and quantitative composition

Each suppository contains:
Hydrocortisone Acetate BP 5 mg
Lidocaine USP 60 mg

3. Pharmaceutical form

White opaque bullet shaped suppositories

4. Clinical particulars

4.1 Therapeutic indications

Anomex Plus Suppositories are indicated for use in the treatment of internal haemorrhoids, pruritus ani, Milder forms of anal fissures, proctitis, pain and discomfort after haemorrhoidectomy

4.2 Posology and method of administration

Adults, elderly and children above 12 years:
One Anomex Plus suppository to be inserted twice a day (morning and evening) and if required after each bowel movement, or as prescribed by the doctor.
Treatment should be limited to seven days. Patients should be advised to return to their doctor if the condition persists beyond this time.

4.3 Contraindications

Anomex Plus Suppositories are contraindicated in patients with known hypersensitivity to any of the constituents of the product. This product is contraindicated in tuberculosis, anal thrush and most viral lesions of the skin including herpes simplex, vaccinia and varicella.

4.4 Special warnings and precautions for use

Anomex Plus Suppositories are not recommended for use in children below 12 years unless recommended by a doctor.
Prolonged and excessive use of hydrocortisone may produce local effects such as skin atrophy. If irritation or rectal bleeding develops, treatment with

Anomex Plus should be discontinues. The patient should be examined and therapy instituted. Excessive dosage of lidocaine or short intervals between doses may result in high plasma, level of lidocaine and serious adverse effects.

4.5 Interaction with other medicinal products and other forms of interaction

With large doses of Lidocaine, consideration should be give the risk of additional systemic toxicity in patients receiving other local anaesthetics or agents structurally related to local anaesthetics. Patients treated with class III antiarrhythmic drugs (e.g.amiodarone) should be closely monitored and ECG monitoring should be considered, since cardiac effects may be additive.

4.6 Pregnancy and Lactation

There is inadequate evidence of safety in human pregnancy. Animal studies are not complete concerning effects on pregnancy, embryonal development, delivery and development after birth. The lowers dose possible and the shortest possible duration of treatment should be aimed at during treatment with Anomex Plus during pregnancy.
Lidocaine and hydrocortisone are excreted in the breast milk in small amounts. Any effect on the nursing infant seems unlikely at therapeutic doses of Anomex-Plus.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

The possibility of systemic absorption should be borne in mind when prescribing preparations containing corticosteroids which can cause adrenal suppression in large doses. Hypersensitivity reactions may occur to some extent**.**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product

4.9 Overdose

Systemic absorption of lidocaine may occur from the rectum.

Lidocaine can cause acute toxic effects if high systemic levels occur due to rapid absorption or overdosage. With the recommended doses of Anomex Plus, toxic effects have not been reported. On rare occasions convulsions have occurred in children following administration of overdose.

However, should systemic toxicity occur, the signs are anticipated to be similar in nature to those following the administration of local anaesthetics by other routes.

Local anaesthetic toxicity is manifested by symptoms of nervous system excitation and, in severe cases, central nervous and cardiovascular depression.

Severe neurological symptoms (convulsions, CNS depression) must be treated symptomatically by respiratory support and the administration of anticonvulsive drugs.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The principle pharmacological actions of hydrocortisone are on gluconeogensis, glycogen deposition, protein and calcium metabolism and inhibition of corticotrophin secretion and anti-inflammatory activity (glucocorticoid actions). When applied topically hydrocortisone causes reduction of inflammation, pruritus and exudation in disorders of the skin and perianal region.
Lidocaine has analgesic effects and acts via reversible block of the impulses from the nerve fibres.

5.2 Pharmacokinetic properties

Hydrocortisone is passed through the skin, particularly in denuded areas. About 90% of plasma hydrocortisone is bound to plasma proteins, mainly to globulin, less so to albumin. In the liver and most body tissues it is metabolised to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These degraded forms are excreted in the urine. They are mainly conjugated as glucuronides. A very small proportion of unchanged hydrocortisone is excreted in the urine. Lidocaine is eliminated primarily through metabolism. Lidocaine crosses blood brain barrier and the placenta, this probably takes place through passive diffusion.

5.3 Preclinical safety data

Lidocaine and hydrocortisone acetate are well established active ingredients.

In animal studies the toxicity noted after high doses of lidocaine consisted of effects on the central nervous and cardiovascular systems. No drug-related adverse effects were seen in reproduction toxicity studies, neither did lidocaine show a mutagenic potential in either in vitro or in vivo mutagenicity tests. Cancer studies have not been performed with lidocaine, due to the area and duration of therapeutic use for this drug.

Genotoxicity tests with lidocaine showed no evidence of mutagenic potential. A metabolite of lidocaine, 2,6-xylidine, showed weak evidence of activity in some genotoxicity tests. The metabolite 2,6-xylidine has been shown to have carcinogenicity potential in preclinical toxicological studies evaluating chronic exposure. Risk assessments comparing the calculated maximum human exposure from intermittent use of lidocaine, with the exposure used in preclinical studies, indicate a wide margin of safety for clinical use.

6. Pharmaceutical Particulars

6.1 List of Excipients

Aluminium Sub Acetate, Zinc Oxide & Hard Fat witepsol W-25

6.2 Incompatibilities

None reported.

6.3 Shelf-Life

2 years when stored between 2° C and 8° C.

2 months when stored below 25° C.

6.4 Special Precautions for storage

Store at 5^0 (2^0-8^0 C). Do not freeze. Protect from light. During treatment the consumer can store Anomex Plus suppositories at room temperature (250 C) for two months.

6.5 Nature and Content of container

5 Suppositories in a strip of ALU/PE foil. 2 strips of 5 suppositories in an inner carton. 20 such inner cartons in an outer carton. 24 such outer cartons packed into one 7 ply shipper.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing Authorization Holder

102, Hyde Park, Saki Vihar Road, Andheri (E), Mumbai - 400 072.

8. Marketing Authorization Number

CTD7187

9. Date of first authorization/renewal of the authorization

3rd March 2023

10. Date of revision of the text

11th May 2025