SUCRAO

Sucralfate & Oxetacaine Oral Suspension

COMPOSITION:

Each 10 ml contains:

Sucralfate USP 1000 mg Oxetacaine 20 mg

In a flavoured sorbitol base a.s. Colour: Sunset Yellow FCF

Sucra O contains combinations of Sucralfate and Oxetacaine for the treatment of acidity, stomach ulcer, and heartburn.

PHARMACODYNAMIC PROPERTIES:

Sucralfate: This drug aids in the healing of duodenal ulcers, relieving painful inflammation by creating a protective mechanical barrier between the lining or ski n of the gastrointestinal tract and damaging substances. In addition, sucralfate acts to increase levels of growth factors locally, and also causes an increase in prostaglanding which are important in the healing of the mucosa (lining) of the gastrointestinal

tract Oxetacaine: Improves common gastrointestinal symptoms. Oxetacaine

is part of the anesthetic antacids which increase the gastric pH while providing relief from pain for a longer period of duration at a lower dosage. This property has been reported to relieve the symptoms of hyperacidity. In vitro, oxetacaine was showed to produce an antispasmodic action on the smooth muscle and block the action of serotonin. The local efficacy of oxetacaine has been proven to be 2000 times more potent than lignocaine and 500 times more potent than cocaine. Its anesthetic action produces the loss of sensation which can be explained by its inhibitory activity against the nerve impulses and de decrease in permeability of the cell membrane.

PHARMACOKINETIC PROPERTIES:

Sucralfate:

Absorption: This drug is absorbed from the gastrointestinal tract in very minimal quantities. The adsorbed sulfated disaccharide is excreted in the urine. This drug contains aluminum and after the administration of 1 g of sucralfate 4 times per day, about 0.001% to 0.017% of this aluminum content is absorbed in patients with normal renal function.

Metabolism: This drug is absorbed in very small quantities and is not significantly metabolized.

Elimination: The negligible amount of this drug that is absorbed is excreted mainly in the urine within 48 hours.

Oxetacaine:

Absorption: A peak plasma concentration of oxetacaine of approximately 20 mg/ml is attained about one hour after oral administration. Less than 1/3 of the administered dose is absorbed as it undergoes extensive metabolism.

Metabolism: Oxetacaine is rapidly and extensively metabolized hepatically. After metabolism, there is a formation of primary metabolites such as beta-hydroxymephentermine and beta-hydroxyphentermine. The major metabolites are found in the plasma in insignificant amounts

Elimination: Less than 0.1% of the administered dose is recovered in urine within 24 hours in the form of unchanged oxetacaine or its metabolites.

INDICATION:

Sucralfate and Oxetacaine is used in the treatment of acidity, heartburn and stomach ulcers.

DOSAGE AND ADMINISTRATION:

As directed by the Physician.

CONTRAINDICATION:

Contraindicated in patients with known hypersensitivity.

SPECIAL WARNING AND PRECAUTION FOR USE:

You should avoid taking Sucralfate & Oxetacaine if you are allergic to Sucralfate & Oxetacaine or other ingredients present in it. Inform your doctor before taking Sucralfate & Oxetacaine if you have a

history of appendicitis, blockage of the bowel, rectal bleeding, kidney problems, low-magnesium diet, or if you have undergone recent bowel surgery. Caution is required before giving Sucralfate & Oxetacaine to

elderly patients.

Sucralfate in Sucralfate & Oxetacaine Oral Suspension contains aluminium, which is normally removed by your kidney. Therefore, older adults and people who have kidney problems may be at greater risk for

developing high aluminium levels while using this drug with other products that contain aluminium (e.g. antacids). Do not take Sucralfate & Oxetacaine if you are pregnant or breastfeeding unless prescribed by the doctor. Avoid consuming alcohol along with Sucralfate & Oxetacaine as it could lead to increased acidity.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

Drug-Drug Interactions: Sucralfate & Oxetacaine interact with the antacid drug (aluminium hydroxide, magnesium hydroxide), anti-HIV drug (dolutegravir), vitamin D analogs (doxercalciferol, paricalcitol), antibiotic (ciprofloxacin, gemifloxacin, levofloxacin), antidiabetic (acarbose, metformin, glipizide, glimepiride, glyburide), blood thinner (warfarin).

Food interactions: Drinking alcohol and nicotine (tobacco) with Sucralfate & Oxetacaine may cause dehydration and elevate the level of stomach acid thereby decreasing Sucralfate & Oxetacaine efficacy. Drug-Disease Interactions: Before taking Sucralfate & Oxetacaine it is better to inform your doctor if you have any kidney or liver disease as a dose of Sucralfate & Oxetacaine needs to be adjusted.

PREGNANCY AND LACTATION

Pregnancy

Sucralfate & Oxetacaine is given to pregnant women only if the doctor thinks benefits outweigh risks. Breast-feeding

The excretion of Sucralfate & Oxetacaine in human milk is unknown. Sucralfate & Oxetacaine is given to breastfeeding women only if the doctor thinks benefits are greater than risks. Please consult a doctor before taking Sucralfate & Oxetacaine if you are breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Sucralfate & Oxetacaine decrease alertness, affect your vision, or make

you feel sleepy and dizzy. Do not drive if these symptoms occur.

UNDESIRABLE EFFECTS: Constipation, Dizziness, Sleepiness, Allergic reaction, dry mouth, upset

stomach, gas & nausea

OVERDOSE:

Never take more than the prescribed dose. Seek immediate medical attention in case of an overdose with Sucra O.

INCOMPATIBILITY:

Not applicable.

SHELF LIFE:

36 Months

PACKAGING:

100 ml amber coloured PET bottle is packed in a printed carton along with pack insert.

STORAGE CONDITION:

Store at temperature below 30°C. Protect from light and moisture. Keep out of reach of children.

SHAKE WELL BEFORE USE

MANUFACTURED BY:

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