Catidral®

SACHETS

Diosmectite 3 g + electrolytes 20-30 sachets of powder for extemporaneous oral suspension

Single use medical device $\mathcal{L}_{\mathfrak{o}_{373}}$

GLUTEN FREE

COMPOSITION

One sachet of powder contains diosmectite 3.00 g, sodium chloride 0.263 g, potassium chloride 0.0373 g, tripotassium citrate anhydrous 0.162 g, trisodiuritate 0.147 g, glucose (dextrose anhydrous) 1.982 g. Excipients: vanillin, sodium, saccharin, silicon dioxide, cream flavouring, vanilla flavouring; dye: beta-carotene.

DESCRIPTION OF THE DEVICE AND INSTRUCTIONS FOR USE

CATIDRAL® is a single use device in sachets of powder for extemporaneous oral suspension. Each sachet must only be used once after opening. The contents of one sachet should be dissolved in 100 ml of water. To obtain a homogeneous suspension, pour the powder into a glass, add water and slowly stir. It is recommended that CATIDRAL® be taken between meals.

INDICATIONS

Oral treatment of acute and chronic diarrhea and the painful symptoms associated with gastrointestinal diseases. CATIDRAL® is indicated for the prophylaxis of diarrhea due to radiotherapy and chemotherapy.

RECOMMENDED DOSE

For the first three days:

Children (1 to 12 months): up to 2 sachets per day (the content of the sachet may be dissolved in baby bottle and divided into 2-3 doses per day).

Children >1 year: up to 4 sachets per day.

Adults: up to 6 sachets per day.

Then continue with halved dosage until the full resolution of diarrhea

DURATION OF THE TREATMENT

CATIDRAL® should not be used for more than 5 consecutive days. If symptoms persist, consult a doctor.

HOW CATIDRAL® ACTS

One sachet of CATIDRAL® contains diosmectite and electrolytes. Diosmectite is a sort of natural clay characterized by a crystalline structure of very thin superimposed strips that give it a high absorption strength, allowing diosmectite to incorporate liquids in the intestinal lumen and thus increasing the consistency of excretion and slowing down expulsion. In this manner CATIDRAL® can also decrease the risk of dehydration due to diarrhea and help the hydrosaline balance return to normal, thanks to the product's balanced dose of electrolytes. Diosmectite's absorption strength also allows CATIDRAL® to interact with glycoproteins in the mucous membrane covering the gastroduodenal wall, by modifying their physical characteristics and generating a protective gel that protects against the hypersecretion of acids and gastro-damaging substances.

SAFETY AND CHECKS BEFORE USE

Seek medical advice in case of concomitant therapies. Keep CATIDRAL® out of the reach of children. Do not use CATIDRAL® if the original packaging is not completely intact. Do not use CATIDRAL® after the expiry date indicated on the packaging.

WARNINGS

The high absorption strenght of diosmectite could interfere with the gastrointestinal absorption of certain drugs taken orally. Other orally administered therapies must therefore be taken far from CATIDRAL®. CATIDRAL® should not be taken by people who are suffering from constipation. For those who suffer from diabetes or are following a particular diet, please be aware that CATIDRAL® contains sugars.

SHELF-LIFE AND STORAGE

CATIDRAL® has a shelf-life of 36 months and should note be used after the expiry date indicated on the packaging. CATIDRAL® should be stored at room temperature and avoid exposure to direct sunlight, sources of heat, humidity and contact with water. The expiry date refers to an intact and properly stored product.

MANUFACTURER

Pharma Line S.r.I., Via Bertani 2 - 20154 Milan, Italy

INTERNAL LEAFLET CATIDRAL Rev. 05 of 12/2019

SYMBOLS KEY



SINGLE USE MEDICAL DEVICE



READ INSTRUCTION BEFORE USE



STORE AT TEMPERATURE BETWEEN 0°C AND 40°C



AVOID DIRECT EXPOSURE TO SUNLIGHT AND HEAT SOURCES



AVOID EXPOSURE TO EXCESSIVE HUMIDITY AND CONTACT WITH WATER



WARNING



MANUFACTURER



BATCH NUMBER



EXPIRY DATE