PROPRIETARY NAME AND DOSAGE FORM:

CATIDRAL

(Powder for suspension)

COMPOSITION:
Each 5,8 g sachet contains:
Diosmectite ..... 3 g
Sodium chloride ..... 0,263 g
Potassium chloride ..... 0,0373 g
Tripotassium citrate anhydrous ... 0,162 g
Trisodium citrate ..... 0,147 g
Glucose (dextrose anhydrous) ..... 1,982 g

Excipients: Vanillin, sodium saccharin, silicon dioxide, cream flavouring, vanilla flavouring, dye, beta-carotene.
Contains sugar: glucose (dextrose anhydrous) 1,982 g.
Contains sweetener: sodium saccharin.

Gluten free

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PHARMACOLOGICAL ACTION:
One (1) 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 gives 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 diarrhoea 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.

INDICATIONS:
Assists in the management of acute and chronic diarrhoea and the painful symptoms associated with gastrointestinal disorders.

CONTRAINDICATIONS:
Use of **CATIDRAL** is not recommended if the patient has a hypersensitivity to any of its active or inactive ingredients. Do not use in the case of gastric or intestinal lesions, or in the event of chronic constipation. Do not use in the case of bowel obstruction. The high absorption strength of diosmectite could interfere with the gastrointestinal absorption of certain drugs taken orally (See **'WARNINGS AND SPECIAL PRECAUTIONS'**).

WARNINGS AND SPECIAL PRECAUTIONS:
Do not use **CATIDRAL** if the original packaging is not completely intact. The high absorption strength of diosmectite could interfere with the gastrointestinal absorption of certain drugs taken orally. Other orally administered therapies must therefore not be taken at the same time as **CATIDRAL. CATIDRAL** should not be taken by people who are suffering from constipation. **CATIDRAL** contains glucose (dextrose anhydrous), which may have an effect on the control of your blood sugar if you have diabetes mellitus.

INTERACTIONS:
See **'WARNINGS AND SPECIAL PRECAUTIONS"**.Before using **CATIDRAL**, consult with your healthcare practitioner if you are using any other concomitant medications.

PREGNANCY AND LACTATION:
Safety and efficacy has not been established for use during pregnancy and breastfeeding.

DOSAGE AND DIRECTIONS FOR USE:
CATIDRAL sachets are disposable and must be removed from the box only immediately before taking the product. Each sachet must only be used once after opening. The contents of one sachet should be dissolved in 100 ml of water. The powder will dissolve more rapidly when stirred. It is recommended that **CATIDRAL** be taken between meals.

Recommended dose:
For the first three (3) days:
Children (1 to 12 months):
Up to two (2) sachets per day in divided doses. The dissolved contents can be mixed with baby formula or milk and can be divided into two (2) or three (3) doses per day. Continue with half of the initial dosage until the full resolution of diarrhoea.
Children older than 1 year (12 months):
Up to four (4) sachets per day in divided doses. Continue with half of the initial dosage until the full resolution of diarrhoea.
Adults:
Up to six (6) sachets per day in divided doses. Continue with half of the initial dosage until the full resolution of diarrhoea.
Duration of the treatment:

CATIDRAL should not be used for more than (5) consecutive days. If symtoms persists more than five (5) days, consult a doctor.

SIDE EFFECTS:
CATIDRAL can have side effects. No side effects have been reported as yet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

IDENTIFICATION:
Powder before reconstitution: white or almost white powder. After reconstitution: suspension with light yellow colour and vanilla flavour.

PRESENTATION:
The powder is packed in polyethylene coated paper sachets. The sachets are further packed in a pre-printed cardboard box with a packaging leaflet.
Pack size: 20 x 5,8 g sachets.

STORAGE INSTRUCTIONS:
CATIDRAL has a shelf-life of 36 months and should not be used after the expiry date indicated on the packaging. The expiry date refers to an intact and properly stored product. **CATIDRAL** should be stored at or below 40 °C and avoid exposure to direct sunlight, sources of heat, humidity and contact with water.

KEEP OUT OF REACH OF CHILDREN.

Symbols key

	SINGLE USE POWDER SACHETS
	READ INSTRUCTIONS BEFORE USE
0°C 40°C	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
LOT	BATCH NUMBER
	EXPIRY DATE

HCR and Manufacturer
Wellness Industries Srl.
Via Giangiacomo Mora, 11/a – Milan, Italy.

INTERNAL LEFLET **CATIDRAL** REV. NR. 05/02/2019