Loperamide Capsules Anti-Dirrhea

COMPOSITION
Each hard gelatin capsule contains:
Loperamide Hydrochloride BP....2 mg
Excipients.....Q.S.
Approved colour used in empty capsule shell.

PHARMACEUTICAL FORM
Hard gelatin capsule, containing white to off white colored powder.

CLINICAL PARTICULARS
Therapeutic indications
For the symptomatic treatment of acute diarrhoea of any aetiology including acute exacerbations of chronic diarrhoea for periods of up to 5 days in adults and children over 9 years. For the symptomatic treatment of chronic diarrhoea in adults.

Posology and method of administration
Posology
Acute diarrhoea
Adults and children over 12 years
Two Capsules(4 mg) initially, followed by one Capsules(2 mg) after every loose stool. The usual dosage is 3-4 Capsules (6 mg-8 mg) per day. The maximum daily dose should not exceed 8 Capsules(16 mg).
Children 9 to 12 years
One Capsules (2 mg) four times daily until diarrhoea is controlled (up to 5 days). This dose should not be exceeded.
Further investigation into the cause of the diarrhoea should be considered if there is no improvement within two days of starting treatment with loperamide.
Chronic diarrhoea
Adults
Patients may need widely differing amounts of loperamide. The starting dose should be between two and four Capsules per day in divided doses, depending on severity. If required, this dose can be adjusted according to result up to a maximum of eight Capsules daily.
Having established the patient's daily maintenance dose, loperamide may be administered on a twice daily regimen. Tolerance has not been observed and therefore subsequent dosage adjustment should be unnecessary.
Elderly
No dose adjustment is required for the elderly.
Renal impairment
No dose adjustment is required for patients with renal impairment.
Hepatic impairment
Although no pharmacokinetic data are available in patients with hepatic impairment, loperamide should be used with caution in such patients because of reduced first pass metabolism
Method of administration
Oral use. The Capsules should be taken with liquid.

Effects on ability to drive and use machines
Loperamide hydrochloride has moderate influence on the ability to drive and use machines. Loss of consciousness, depressed level of consciousness, tiredness, dizziness or drowsiness may occur when diarrhoea is treated with loperamide hydrochloride.
Therefore, it is advisable to use caution when driving or operating machinery.

Overdose
Symptoms
In case of overdose (including relative overdose due to hepatic dysfunction), CNS depression (stupor, coordination abnormality, somnolence, miosis, muscular hypertonia, and respiratory depression), urinary retention and ileus may occur. Children may be more sensitive to CNS effects than adults.
In individuals who have ingested overdoses of loperamide HCl, cardiac events such as QT interval prolongation, torsades de pointes, other serious ventricular arrhythmias, cardiac arrest and syncope have been observed. Fatal cases have also been reported. Overdose can unmask existing Brugada syndrome.
Treatment
If symptoms of overdose occur, naloxone can be given as an antidote. Since the duration of action of loperamide is longer than that of naloxone (1 to 3 hours), repeated treatment with naloxone might be indicated. Therefore, the patient should be monitored closely for at least 4 hours in order to detect possible CNS depression.

STORAGE:
Store below 30°C in dry place. Protect from light.

KEEP THE MEDICINES OUT OF REACH OF CHILDREN.

Presentation:
A box containing 1 Blister of 10 Capsules each.

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