

Relmas[®] 10

Baclofen

COMPOSITION:

Relmas[®] 10 tablet: Each tablet contains Baclofen BP 10 mg.

PHARMACOLOGY:

Baclofen is a muscle relaxant and antispastic. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level by stimulating the GABAB-receptors, which inhibits the release of glutamate and aspartate. It may also act at intraspinal sites producing CNS depression. Baclofen also exerts an antinociceptive effect.

INDICATION:

Relmas[®] is indicated for

- Spasticity resulting from multiple sclerosis
- Flexor spasms and concomitant pain, clonus and muscular rigidity
- Skeletal muscle spasm resulting from rheumatic disorders.
- Spinal cord injuries and other spinal cord diseases.
- Cerebrovascular accidents or neoplastic or degenerative brain disease.

DOSE & ADMINISTRATION:

Adults:

Start therapy at low dosage and increase gradually until optimum effect is achieved (usually between 30 - 80mg daily). The following dosage titration schedule is suggested: - 5 mg three times a day for 3 days. - 10 mg three times a day for 3 days. - 15 mg three times a day for 3 days. 20 mg three times a day for 3 days. Thereafter additional increases may be necessary, but the total dose should usually not exceed a maximum of 80 mg, although in hospitalised patients daily doses of 100 - 120 mg may occasionally be necessary.

Children:

Treatment should be started at a very low dose e.g. 0.3 mg/kg per day in divided doses. The dosage should be raised cautiously at 1-2 week intervals until it is sufficient for the child's individual needs. The usual dosage range for maintenance therapy is 0.75 to 2 mg/kg body weight per day. In children aged over 10 years a maximum daily dose of 2.5mg/kg bodyweight may be given.

CONTRA-INDICATION:

Baclofen is contraindicated In patients with hypersensitivity to any component of this product.

WARNING AND PRECAUTION:

Because of the possibility of sedation, patients should be cautioned regarding the operation of automobiles or other dangerous machinery, and activities made hazardous by decreased alertness.

SIDE EFFECTS:

The most common side-effects include drowsiness, nausea, dizziness, confusion, fatigue, weakness, and hypotension. Other side-effects include, hallucinations, depression, headache, tinnitus, paraesthesias, slurred speech, dry mouth, taste alterations, diarrhoea or constipation, tremors, insomnia, respiratory or cardiovascular depression.

USE IN PREGNANCY & LACTATION:

The safety of Baclofen in women who are or who may become pregnant has not been established. Potential benefits should be weighted against possible hazards. Use of Baclofen in lactating women is not recommended.

USE IN CHILDREN & ADOLESCENTS:

Baclofen tablets are not suitable for use in children under 33 kg body weight.

DRUG INTERACTION:

Alcohol and other CNS depressants, lithium, tricyclic antidepressant, Ibuprofen etc.

OVERDOSE:

Gastric lavage is important in case of severe overdose.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Relmas[®] 10 tablet: Each box contains 3x10's tablets in blister pack.



Manufactured by

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