

BIPAX® Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about BIPAX

Each coated tablet of BIPAX contains:

Chlordiazepoxide 5 mg

Clidinium bromide 2.5 mg

BIPAX tablets are for oral use.

Chlordiazepoxide is a benzodiazepine which relieves anxiety and tension and has a muscle-relaxant action and weak analgesic actions.

Clidinium bromide is an anticholinergic having antispasmodic effect on smooth muscle and inhibits secretion.

BIPAX is effective on symptoms observed in functional disorders of the gastrointestinal and genitourinary tracts caused by anxiety and tension.

BIPAX is effective as adjunctive therapy in the treatment of peptic ulcer, irritable bowel syndrome (irritable colon, spastic colon) and acute enterocolitis. BIPAX is also effective for the treatment of functional manifestations of hypersecretion and hypermotility, gastritis, duodenitis, biliary dyskinesia, diarrhea, nocturnal enuresis, irritable bladder and dysmenorrhea.

The way to take BIPAX

Take BIPAX as directed by your physician. Do not discontinue the treatment without consulting your doctor. Dosage and duration of treatment are individualized on the basis of the condition under treatment and the response of the patient.

The usual recommended maintenance dose for adults is 1 or 2 tablets, 3 or 4 times a day administered before meals and at bedtime.

In dysmenorrhea, BIPAX should be administered during the three or four days preceding the expected menstruation date.

In elderly patients, the dosage is limited to the smallest effective and tolerated amount.

Duration of treatment

It may take 4 to 5 days of regular use to determine the effectiveness of the drug. As long as this drug is tolerable, it can be taken for long-term with physician supervision. Usually, treatment should not exceed 8 to 12 weeks.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following cases:

- known hypersensitivity to any of the components
- glaucoma
- prostatic hypertrophy
- urinary retention
- severe hepatic failure

Precautions

- Because of its sedative effects, you should not operate heavy machinery, drive, or engage in other hazardous tasks that require you to be mentally alert while you are taking this drug.
- Consult your doctor before either increasing the dose or discontinuing the drug. He may want you to discontinue the drug gradually rather than abruptly.
- This drug should not be used during pregnancy and lactation.

- This drug must be used with caution in case of impaired renal or hepatic function, respiratory disease, cardiovascular disease, hyperthyroidism, myasthenia gravis and in psychiatric patients.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

In general, the concomitant administration with other psychotropic agents is not recommended.

Use with caution with alcohol, cimetidine, central nervous system depressants (antipsychotics, tranquilizers, anti-depressants, hypnotics, opioid analgesics), oral anticoagulants and anticholinergics (antihistamines H1, neuroleptics, antispasmodics, antidepressants).

Adverse reactions

This drug is usually well tolerated in therapeutic doses. The most reported side effects include dryness of the mouth, constipation, headache, drowsiness, dizziness, irritability, palpitations, allergic reactions, confusion, blurred vision, urinary retention and dependence.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

BIPAX, chlordiazepoxide 5 mg and clidinium bromide 2.5 mg, pack of 30 tablets

Revision date: 06/2010

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