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Schircks Laboratories

TETRAHYDROBIOPTERIN TABLETS

Product

Tetrahydrobiopterin tablets are packed in blisters. Each blister contains 10 tablets. The blisters are packed in cartons of 1 or 10 blisters. Please see our price lists.

Composition

Each 10 mg tablet contains:

10 mg (6R)-5,6,7,8-tetrahydro-L-biopterin dihydrochloride*
 (6R-BH₄·2HCl)

10 mg ascorbic acid

and other excipients (no lactose is added and no materials are used that are derived from animal or cell culture techniques)

* INN: Sapropterin dihydrochloride

Each 50 mg tablet contains:

50 mg (6R)-5,6,7,8-tetrahydro-L-biopterin dihydrochloride*
 (6R-BH₄·2HCl)

50 mg ascorbic acid

and other excipients (no lactose is added and no materials are used that are derived from animal or cell culture techniques)

Properties

Tetrahydrobiopterin is a naturally occurring cofactor of the aromatic amino acid hydroxylases and is involved in the synthesis of tyrosine and the neurotransmitters dopamine and serotonin.

Indications

Tetrahydrobiopterin tablets are used clinically worldwide in the diagnosis and treatment of BH₄ deficiency and BH₄ responsive HPA/PKU.

Contraindications

There are no contraindications known and no serious side effects were noted (please see our Summary of Product Characteristics (SPC) for tetrahydrobiopterin). Inadequate clinical data on exposed pregnancies is available.

Administration and dosage

Orally 1 to 20 mg tetrahydrobiopterin/kg/day. The dosage given depends on the type and degree of tetrahydrobiopterin deficiency. The tetrahydrobiopterin should be administered in 2-3 daily doses in order to optimize the therapeutic response.

Dissolve the tablets in a little water, orange juice or infant formula, mixing it gently. Administer the suspension within 30 minutes. Older children and adults may swallow the tablets undissolved.

Recommendations

The placing of a single order for an 8 month supply of tetrahydrobiopterin tablets is recommended as the tablets themselves cost less when ordered in large quantities (please see our price list) and courier charges would be paid by us for such orders.

Storage

Keep the blisters at about -20°C.

Tetrahydrobiopterin dihydrochloride is hygroscopic and reacts with oxygen.

In a freezer (-20°C or colder) tetrahydrobiopterin tablets may be kept for three years.

If a freezer is not available, a freezer compartment of a fridge can also be used. Failing that, a fridge may be used. Please note the stability differences of each of the above.

Freezer (-20°C or colder):	36 months
Freezer compartment of a fridge (-10°C or colder):	18 months
Fridge (+5°C or colder):	4 months

If the tablets have been stored for more than six months at 25°C, they may become slightly yellow or they may tend to break easily. But they still have at least 99.5% of the original content of sapropterin dihydrochloride. The tablets can be frozen then thawed and then refrozen without any adverse affect. **The expiry date on the tablets has been set to allow for up to 2 months storage at room temperature.**

Please note that further information, SPC for tetrahydrobiopterin, price lists, data sheets and ordering guidelines can be found on our website www.schircks.com. It is also linked to the tetrahydrobiopterin website www.bh4.org which provides detailed information on tetrahydrobiopterin deficiencies and their treatment.