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TECHNICAL DATA SHEET

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80772-BUPROPION HYDROCHLORIDE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.

Name: Bupropion Hydrochloride

Bulk code: 80772

1.2 Synonims.

Amfebutamone HCI; BW-323.

2. DESCRIPTION

Appearance: Crystalline powder. Colour: White or almost white.

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: C₁₃H₁₈ CINO.HCl

CAS: 31677-93-7 (bupropion hydrochloride)

Molecular weight: 276.20 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: In water and in alcohol.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

Bupropion is a chloropropiophenone with antidepressant action.

It is a weak serotonin and noradrenaline reuptake inhibitor compared to tricyclic antidepressants. Another characteristic is that it inhibits neuronal dopamine reuptake.

It is used to treat depression and to help quit smoking.



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6. DOSAGE.

Orally:

- For depression treatments, the starting doses are 100 mg of Bupropion HCl, twice a day. If necessary, this dose may be increased to three daily doses starting from the third day.
- In severe cases where no improvement is observed after several weeks of treatment, the dose may be increased to a maximum of 150 mg three times a day.
- In smoking cessation therapies, it is used in doses of 150 mg once a day for 6 days. After the seventh day, 150 mg is administered twice a day. Treatment is maintained for 7 to 12 weeks, although if there is no improvement by the 7th week, treatment should be discontinued.

It is recommended to increase the dose gradually in order to decrease the agitation, anxiety and insomnia that appear at the beginning of treatment and to reduce the risk of seizures. The total daily dose should be administered in divided doses throughout the day and should not exceed the maximum recommended dose.

Avoid taking at bedtime to decrease the insomnia that appears at the beginning of therapy.

7. REMARKS.

STORAGE:

Store at room temperature (25±2°C), in a cool, dry place, away from sunlight, in a tightly closed container.

8. BIBLIOGRAPHY.

Remington. Pharmacy. Ed. Panamericana, 17th edition. MICROMEDEX. Martindale – The Complete Drug Reference.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993)