Abbreviated Prescribing Information

CINRYZE® 500 IU powder

C1 esterase inhibitor (human)

Qualitative and Quantitative Composition: Each single use powder vial contains 500 International Units (IU) of C1 inhibitor (human) produced from the plasma of human donors, Trisodium citrate dihydrate 14.7 mg, sodium chloride 20.5 mg, L-valine 10.3mg, L-analine 6mg, L-theronine 23.5 mg and sucrose 100mg. **Clinical Particulars: Therapeutic indications**: Treatment of angioedema attacks in adults, adolescents and children 2 years of age and above with hereditary angioedema (HAE). Pre-procedure prevention of angioedema attacks in adults, adolescents and children 2 years of age and above with hereditary angioedema (HAE). Routine prevention (prophylaxis) of angioedema attacks in adults, adolescents and children 6 years of age and above with hereditary angioedema (HAE). **Posology and Method of Administration:** CINRYZE® therapy is for intravenous route only. Patients may also administer CINRYZE® after training under the guidance of health care professional. The reconstituted product should be inspected fir particulate matter prior to administration (do not infuse if particles are seen). The reconstituted product should be administered by intravenous injection at a rate of 1 ml per minute. *Treatment of angioedema attacks: Adult & adolescents (12 to 17 years old):* 1000 IU of CINRYZE® at the first sign of the onset of an angioedema attack. A second dose of 1000 IU may be administered if the patient has not responded adequately after 60 minutes. *For children 2 to 11 years who weigh > 25 kg:* 1000 IU of CINRYZE® at the first sign of the onset of an angioedema attack. A second dose of 1000 IU may be administered if the patient has not responded adequately after 60 minutes. *For children 2 to 11 years who weigh between 10-25 kg:* 500 IU of CINRYZE® at the first sign of the onset of an angioedema attack. A second dose of 500 IU may be administered if the patient has not responded adequately after 60 minutes. *Pre procedure Prevention of angioedema attacks. Adult & adolescents (12 to 17 years old):* 1000 IU of CINRYZE® within 24 hours before a medical, dental or surgical procedure. *For children 2 to 11 years who weigh > 25 kg:* 1000 IU of CINRYZE® within 24 hours before a medical, dental or surgical procedure. *For children 2 to 11 years who weigh between 10-25 kg:* 500 IU of CINRYZE® within 24 hours before a medical, dental or surgical procedure. Routine prevention of angioedema attacks*. Adults and adolescents (12 to 17 years old):* 1000 IU of CINRYZE® every 3 or 4 days for routine prevention against angioedema attacks. Doses up to 2,500 IU every 3 to 4 days may be considered based on individual patient response. *Children 6 to 11 years of age:* 500 IU of CINRYZE® every 3 or 4 days for routine prevention against angioedema attacks. Doses up to 1000 IU every 3 to 4 days may be considered based on individual patient response. **Contraindications:** CINRYZE® is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis to the product.

Special warnings and precautions for use. Thrombotic events: Thrombotic events have been reported in patients receiving CINRYZE®, and patients with known risk factors should be monitored closely. Transmissible Agents: Standard C is made from the human blood, and it may carry a risk of transmitting infective agents. Hyper-sensitivity: Hypersensitivity reactions may have symptoms like angioedema attacks. **Interaction with other drugs**: No interaction studies have been conducted. **Fertility, Pregnancy, and Lactation Pregnancy:** It is not known that CINRYZE® when administered to a pregnant women can harm fetus or can affect reproduction capacity. CINRYZE® should be given to pregnant women only when clearly indicated. It is not known whether CINRYZE® is excreted in human milk, and caution must be exercised when it is administered during lactation. **Effects on Ability to Drive and Use Machines:** Based upon the clinical data currently available, CINRYZE® has a minor influence on the ability to drive and use machines. **Undesirable Effects:** The very common adverse reactions following CINRYZE®

infusion include headache and nausea. The common adverse reactions include hypersensitivity, dizziness, rash, erythema, pruritus, injection site reactions and pyrexia. The uncommon adverse reactions include hot flush, phlebitis, venous burning and venous thrombosis**. Storage and handling instructions:** Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light. After reconstitution use the reconstituted product immediately. If immediate use is not possible, chemical and physical in use stability has been demonstrated for 3 hours at room temperature (15^0C -25^0C) For storage conditions after reconstitution of the medicinal product.

Manufactured by:

Takeda Manufacturing Austria AG, Industriestrasse 67,1221 Vienna, Austria

Name and Address of Imported and Marketed by :

Baxalta Bioscience India Pvt. Ltd,
Khasra No. 1/24, 25, 3/1/1, Gala No. 1A-1F, 2A-2E,
3B-3E and 4A-4E, Warehouse No. 1, Sector-76,
Hasanpur Darbaripur, Gurgaon, Haryana India

Suspected Adverse Reactions should be reported at: AE.India@takeda.com.

Consumer Care No: 00080 0050 4087

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Further information is available on request.

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