

**Cinacalcet-TrimaFilm Coated Tablets, 30/60/90mg
Cinacalcet (as Hydrochloride) 30/60/90 mg**

Manufacturer: **Trima Israel Pharmaceutical Products
Maabarot Ltd.**

Dossier status: Complete CTD file

Dossier date: Dossier ready, submitted to Israeli MOH
on 06/2014 and approved October 2015.

Dosage form: Tablets

Bioequivalence reference:

The reference product is MIMPARA 90mg, Film Coated Tablets (Cinacalcet HCl 90mg)), manufactured by AMGEN Europe B.V. Breda Netherlands. Source country: Israel.

Stability data: 3 batches, 6 months at 40°C, 75% RH
3 batches, 3 years at 25°C, 60% RH

Packaging: Tablets packed in blister packs comprised
of PVC and Aluminum foil.

The European Union (EU) has in place an agreement (2013/1/EU) on conformity assessment and mutual acceptance of Pharmaceutical Good Manufacturing Practice (GMP) with Israel. The Trima manufacturing facility is therefore considered as EU-GMP compliant.

For further information, please contact:

Products protected by patents in force are neither offered for sale nor marketed in jurisdictions where such activities would constitute patent infringement.

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