Product information sheet January 2017

Desloratadine-Trima Syrup, 0.5mg/ml

Desloratadine 0.5 mg/ml

Manufacturer:	Trima Israel Pharmaceutical Products Maabarot Ltd.
Dossier status:	Complete CTD file
Dossier date:	Dossier is ready, submitted to Israeli MOH 10/2012, approved August 2013.
Dosage form:	Syrup

Bioequivalence reference: None.
Bioequivalence study was not required due to a waiver received from Israeli MOH (the active substance produces a true aqueous solution in a low acidic environment. pH=5.5)

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

Packaging: 125ml bottle amber glass type III with childproof cap

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:

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