

Tinden GelActive ingredient : **Dimetindene Maleate** 0.1% W/W(Equivalent to Fenistil, Novartis TM)

Manufacturer	Trima Israel Pharmaceutical Products Ltd.
Dossier Type	CTD
Dossier Status	Dossier ready, submitted to Israeli MOH in April 2016 and approved in July 2018
Dosage form	Gel, topical.
Bioequivalence reference	Not applicable (OTC product).
Stability data	<p>Pilot batches were packed in Alu/Alu blister packs and incubated under the following conditions:</p> <p>40°C/75%RH for 6 months</p> <p>30°C/65%RH for up to 21 months</p> <p>25°C/60%RH for up to 21 months</p> <p>According to the finished dosage manufacturing procedures, the first three commercial batches will go into long term stability study. After that, an additional one batch a year will join the long term stability study.</p>
Packaging:	Aluminium tube, 30 G.

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:-

INTERPHARM
CONSULTANCY 

Peter Wittner B.Sc
Direct line: +972 58 773 4238
E-mail: peter@interpharm-consultancy.co.uk
web: www.interpharm-consultancy.co.uk

9c Szold Street,
Raanana, Israel 43218
Phone: +44 20 8446 5572

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

INTERPHARM