## PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON

#### 1. NAME OF THE MEDICINAL PRODUCT

Tomonil 1.5 mg tablet levonorgestrel

#### 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 1.5 mg of levonorgestrel

#### 3. LIST OF EXCIPIENTS

This medicinal product contains lactose monohydrate. Read the package leaflet before use.

#### 4. PHARMACEUTICAL FORM AND CONTENTS

tablet 1 tablet

#### 5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

To be swallowed.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

#### 7. OTHER SPECIAL WARNING(S), IF NECESSARY

If you have used certain other medicines in the last 4 weeks, especially treatment of epilepsy, tuberculosis, HIV infection or (traditional) herbal medicine containing St. John's wort (se package leaflet), Tomonil may be less effective. If you use theses medicines, take 2 tablets of Tomonil. If you are unsure or want to ask for an alternative treatment, talk to your doctor or pharmacist before using Tomonil.

#### 8. EXPIRY DATE

EXP.

#### 9. SPECIAL STORAGE CONDITIONS

No special requirements for storage

# 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

NAARI B.V

Kanaalstraat 12 B, 5347KM Oss

The Netherlands

#### 12. MARKETING AUTHORISATION NUMBER(S)

56750

#### 13. BATCH NUMBER

Batch:

#### 14. GENERAL CLASSIFICATION FOR SUPPLY

Not subject to medical prescription

#### 15. INSTRUCTIONS ON USE

#### Front

Emergency contraceptive

#### Back

Indication

Tomonil is an emergency contraceptive used after unprotected intercourse or the contraceptive method has failed.

#### Normal dosage:

Take the tablet as soon as possible after you have had unprotected intercourse but not later than 72 hours (3 days). Should be taken within 12 hours.

#### 16. INFORMATION IN BRAILLE

Tomonil 1.5 mg tablet

#### 17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

#### 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

### PARTICULARS TO APPEAR ON BLISTERS OR STRIPS PVC / ALUMINIUM BLISTER

1. NAME OF THE MEDICINAL PRODUCT
Tomonil 1.5 mg tablet
levonorgestrel
2. MARKETING AUTHORISATION HOLDER
NAARI B.V
3. EXPIRY DATE
EXP.
4. BATCH NUMBER
Batch:
5. OTHER