ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BOTTLE PACK (90 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains lasofoxifene tartrate, equivalent to 500 microgram lasofoxifene.

3. LIST OF EXCIPIENTS

Contains lactose

See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

90 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Sealed pack.

Do not use if box has been opened.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

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

Pfizer Limited

Ramsgate Road

Sandwich

Kent

CT13 9NJ

United Kingdom

12. MARKETING AUTHORISATION NUMBER

EU/0/00/000/000

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

FABLYN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTER PACK (30 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains lasofoxifene tartrate, equivalent to 500 microgram lasofoxifene.

3. LIST OF EXCIPIENTS

Contains lactose

See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Sealed pack.

Do not use if box has been opened.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

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

Pfizer Limited

Ramsgate Road

Sandwich

Kent

CT13 9NJ

United Kingdom

12. MARKETING AUTHORISATION NUMBER

EU/0/00/000/000

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

FABLYN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTER PACK (7 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains lasofoxifene tartrate, equivalent to 500 microgram lasofoxifene.

3. LIST OF EXCIPIENTS

Contains lactose

See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

7 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Sealed pack.

Do not use if box has been opened.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

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

Pfizer Limited

Ramsgate Road

Sandwich

Kent

CT13 9NJ

United Kingdom

12. MARKETING AUTHORISATION NUMBER

EU/0/00/000/000

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

FABLYN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTER PACK (28 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains lasofoxifene tartrate, equivalent to 500 microgram lasofoxifene.

3. LIST OF EXCIPIENTS

Contains lactose

See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

28 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Sealed pack.

Do not use if box has been opened.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

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

Pfizer Limited

Ramsgate Road

Sandwich

Kent

CT13 9NJ

United Kingdom

12. MARKETING AUTHORISATION NUMBER

EU/0/00/000/000

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

FABLYN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER - 28 tablets

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pfizer

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER

Mon

Tue

Wed

Thu

Fri

Sat

Sun

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

FABLYN 500 microgram film-coated tablets

lasofoxifene

For oral use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

90 film-coated tablets

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER - 7 tablets

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pfizer

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER

Mon

Tue

Wed

Thu

Fri

Sat

Sun

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER - 30 tablets

1. NAME OF THE MEDICINAL PRODUCT

FABLYN 500 microgram film-coated tablets

lasofoxifene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pfizer

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

FABLYN 500 microgram film-coated tablets
lasofoxifene

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT FABLYN IS AND WHAT IT IS USED FOR

FABLYN is used to treat osteoporosis in women after the menopause (postmenopausal osteoporosis) who are likely to break bones, especially in the spine, hips and wrists. It belongs to a group of medicines called Selective Estrogen Receptor Modulators (SERM).

In women with postmenopausal osteoporosis, FABLYN reduces the risk of both fractures of the spine (vertebral fractures) and non-spine fractures (non-vertebral fractures), but not hip fractures.

2. BEFORE YOU TAKE FABLYN

Do not take FABLYN
- if you are allergic (hypersensitive) to lasofoxifene or any of the other ingredients of FABLYN.
- if you currently have or previously had blood clots, for example in your veins, lungs or eyes (deep vein thrombosis, pulmonary embolism or retinal vein thrombosis).
- if you have any vaginal bleeding. This must be investigated by your doctor **before starting treatment**.
- if you could still become pregnant.
- if you are pregnant or breast-feeding.

Take special care with FABLYN

- **if you are immobile for some time**, such as, needing to be admitted to a hospital or having to stay in bed while recovering from an operation or an illness, as these may increase your risk of blood clots (deep vein thrombosis, pulmonary embolism or retinal vein thrombosis). **Your doctor may recommend that you stop treatment at least 3 weeks prior to this time.** Treatment with FABLYN can be restarted as soon as you regain your mobility and in consultation with your doctor.

- if you are taking FABLYN, you should walk around or exercise your legs and feet at regular intervals when traveling long distances. This is because sitting for a long time in the same position may prevent good blood circulation and may increase your risk of blood clots.

It is unlikely that FABLYN will cause vaginal bleeding. So any vaginal bleeding while you take FABLYN is unexpected. You should have this investigated by your doctor.

The following are reasons why this medicine may not be suitable for you. **You should talk to your doctor before starting to take FABLYN :**

- if you have or have had breast cancer.
- if you experience any unexplained breast abnormality.
- if you have severe liver disease.
- if you have severe kidney disease.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are taking estrogen replacement therapy (ERT) or hormone replacement therapy (HRT), FABLYN may not be suitable for you.

Taking FABLYN with food and drink

FABLYN can be taken with or without food and drink.

Pregnancy and breast-feeding

FABLYN is only for women after the menopause and must not be taken by women who can still become pregnant.

Do not take FABLYN if you are pregnant or breast-feeding as it might be excreted in mother's milk.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

FABLYN has no known influence on the ability to drive and use machines.

Important information about some of the ingredients of FABLYN

FABLYN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE FABLYN

Always take FABLYN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one tablet each day.

Swallow the tablet whole. You may take it with or without food.

If you wish, you may take it with water or another beverage of choice.

Your doctor may also advise you to take Calcium and Vitamin D supplements while you are treated with FABLYN if your daily intakes are not considered sufficient.

If you take more FABLYN than you should

If you take more tablets than you should, tell your doctor or pharmacist.

If you forget to take FABLYN

Do not take a double dose to make up for a forgotten tablet. Take your next tablet and continue as before.

If you stop taking FABLYN

You should talk to your doctor before stopping FABLYN.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FABLYN can cause side effects, although not everybody gets them.

Most of the side effects that occurred during studies were mild.

These side effects may occur with certain frequencies, which are defined as follows:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000
- Not known: frequency cannot be estimated from the available data

Very common side effects:

- Muscle cramps

Common side effects:

- Hot flush
- Constipation
- Pressure in the lower abdomen
- Vaginal discharge
- Excessive sweating

Uncommon side effects:

- Urinary tract infection, burning on urination, urgent need to urinate, urinary incontinence
- Abdominal pain or pressure, pain in the back, neck, joints or chest
- Tiredness, abnormal or excessive bleeding commonly from the nose
- Diabetes (typical symptoms are excessive thirst, frequent urination)
- Burning sensation, dizziness, numbness, memory impairment, impaired or partial loss of movement of a limb, headache, restless legs syndrome (an irresistible urge to move legs to stop an uncomfortable or odd sensations)
- Abnormal or irregular beating of the heart, increased heart rate
- Swelling of hands, arms, feet or legs, limb pain
- Cough, difficulty breathing, stuffy nose, runny nose
- Dry mouth, flatulence (excessive amount of air or gases in the stomach or the intestine), stomach ache
- Dry eye, hair loss, skin rash, night sweats, itching, feeling hot, weight gain
- Breast stiffening, breast pain, vaginal bleeding, genital itching

Rare side effects:

- Infection in the ear, eye, respiratory tract or skin, diarrhea, blood in stools
- Change in appetite
- Abnormal dreams, mood swings
- Dizziness, altered sense of taste, seizures, migraine, weakness of arms or legs, sciatica (pain felt in the lower back, buttock, and/or various parts of the leg and foot; typically on one side of the body)
- Impaired vision, pain in eyes, itchy eyes, swollen eyelids, redness of the eyes, ear pain
- Lip lesions, change of bowel habits, difficulty swallowing, mouth ulcer, heart burn, mouth pain, anal pain
- Jaundice (yellowing of the skin and eyes), changes in blood tests of liver function
- Dry skin, unusual hair texture, nail disorder, skin rash, skin darkening, altered shape of fingers, skin lesion
- Painful urination, blood in urine
- Breast discharge, breast lump, vaginal pain, varicose vein
- Decreased pulse in feet, bruising

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FABLYN

Keep out of the reach and sight of children.

Do not use FABLYN after the expiry date which is stated on the blister or bottle label and on the carton after "EXP:". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What FABLYN contains

- The active substance is lasofoxifene. Each film-coated tablet contains lasofoxifene tartrate, equivalent to 500 micrograms of lasofoxifene.

- The other ingredients are lactose anhydrous; microcrystalline cellulose; croscarmellose sodium; silica, colloidal anhydrous; magnesium stearate; sunset yellow FCF aluminium lake (E110); hypromellose; lactose monohydrate; titanium dioxide (E171) and triacetin.

What FABLYN looks like and contents of the pack

FABLYN tablets are triangular, peach coloured, film-coated tablets marked with "Pfizer" on one side and "OPR 05" on the other.

The tablets are provided in blister packs containing 7, 28 or 30 tablets, and in bottle packs containing 90 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom.

The Manufacturer is Pfizer Manufacturing Deutschland GmbH, Heinrich Mack Strasse 35, 89257 Illertissen, Germany.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu/.