

**PACKAGE LEAFLET:
INFORMATION FOR THE USER
Telfast 180 mg Film-coated tablets**

Fexofenadine hydrochloride

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 Telfast is and what it is used for
2. Before you take Telfast
3. How to take Telfast
4. Possible side effects
5. How to store Telfast
6. Further information

1. What Telfast is and what it is used for

Telfast contains fexofenadine hydrochloride, which is an antihistamine.
Telfast 180 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. Before you take Telfast

 **Do not take Telfast**

X if you are allergic (hypersensitive) to fexofenadine or any of the other ingredients of Telfast (see section 6 for a full list of ingredients).

 **Take special care with Telfast**

- if you have problems with your liver or kidneys
- if you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- if you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Telfast.

 **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines,

including medicines obtained without a prescription.

Indigestion remedies containing aluminium and magnesium may affect the action of Telfast by lowering the amount of drug absorbed.
It is recommended that you leave about 2 hours between the time that you take Telfast and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Telfast if you are pregnant, unless necessary.

Telfast is not recommended during breast feeding.



Driving and using machines

Telfast is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. How to take Telfast

Always take Telfast exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over

The recommended dose is one tablet (180 mg) daily.

Take your tablet with water before a meal.

If you take more Telfast than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Telfast

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Telfast

Tell your doctor if you want to stop taking Telfast before you have finished your course of treatment.

If you stop taking Telfast earlier than planned, your symptoms may return.



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

4. Possible side effects

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

Tell your doctor immediately and stop taking Telfast if you experience swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Common side effects (occurring in less than 1 in 10 but in more than 1 in 100 patients):
headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but in more than 1 in 1,000 patients):
tiredness/sleepiness.

Additional side effects (frequency unknown), which may occur are: difficulty sleeping (insomnia), sleeping disorders, bad dreams, nervousness, fast or irregular heart beat, diarrhoea, skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing.

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 Telfast

Keep out of the reach and sight of children.

Do not use Telfast after the expiry date which is stated on the over-labelled carton and strips after EXP.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Telfast 180mg contains

The active substance of Telfast is fexofenadine hydrochloride. Each tablet contains 180mg of fexofenadine hydrochloride.

The other ingredients are:

Tablet core: microcrystalline cellulose,

pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

Film coating: hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Telfast 180 mg looks like and contents of the pack

Telfast 180 mg film-coated tablets are peach coloured, capsule shaped tablets marked with "018" on one side and "e" on the other.

Telfast is presented in over-labelled blister packs. Each tablet is blistered.

Telfast is available in packs of 30 tablets per package.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Telfast 180mg filmomhulde tabletten
Denmark: Telfast, filmovertrukne tabletter 180 mg
Finland: Telfast 180mg tabletti, kalvopäällysteinen
Germany: Telfast 180mg
Ireland: Telfast 180 mg film-coated tablets
Italy: Telfast 180 mg compresse rivestite con film
Portugal: Telfast 180, comprimidos revestidos por película
Spain: Telfast 180 mg comprimidos recubiertos con película
Sweden: Telfast 180 mg filmdragerade tabletter
United Kingdom: Telfast 180 mg film-coated tablets

Who has made your medicine?

Telfast 180mg is manufactured by Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37100 Tours, France

Procured from within the EU by the parallel product authorisation holder: McDowell Pharmaceuticals, 4 Altona Road, Lisburn, N. Ireland BT27 5QB, and repackaged by: Cross Healthcare Limited, Unit 2A, Bandearth Ind. Est., Throsk, Stirling, Stirlingshire FK7 7NP, United Kingdom.

Date of leaflet preparation: JUNE 2013

Telfast and Zentiva are registered trademarks of Sanofi Aventis.

PARALLEL PRODUCT AUTHORISATION NUMBER: Telfast 180mg PPA 1473/52/1

REF: C1473/52/1/136

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Telfast 180 mg Film-coated tablets**

Fexofenadine hydrochloride

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1. What Telfast is and what it is used for

Telfast contains fexofenadine hydrochloride, which is an antihistamine.
Telfast 180 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. Before you take Telfast

 **Do not take Telfast**

X if you are allergic (hypersensitive) to fexofenadine or any of the other ingredients of Telfast (see section 6 for a full list of ingredients).

 **Take special care with Telfast**

- if you have problems with your liver or kidneys
- if you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- if you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Telfast.

 **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines,

including medicines obtained without a prescription.

Indigestion remedies containing aluminium and magnesium may affect the action of Telfast by lowering the amount of drug absorbed.
It is recommended that you leave about 2 hours between the time that you take Telfast and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.
Do not take Telfast if you are pregnant, unless necessary.
Telfast is not recommended during breast feeding.



Driving and using machines

Telfast is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. How to take Telfast

Always take Telfast exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over
The recommended dose is one tablet (180 mg) daily.
Take your tablet with water before a meal.

If you take more Telfast than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Telfast

Do not take a double dose to make up for a forgotten tablet.
Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Telfast

Tell your doctor if you want to stop taking Telfast before you have finished your course of treatment.
If you stop taking Telfast earlier than planned, your symptoms may return.



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

4. Possible side effects

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

Tell your doctor immediately and stop taking Telfast if you experience swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Common side effects (occurring in less than 1 in 10 but in more than 1 in 100 patients):
headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but in more than 1 in 1,000 patients):
tiredness/sleepiness.

Additional side effects (frequency unknown), which may occur are: difficulty sleeping (insomnia), sleeping disorders, bad dreams, nervousness, fast or irregular heart beat, diarrhoea, skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing.

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 Telfast

Keep out of the reach and sight of children.

Do not use Telfast after the expiry date which is stated on the over-labelled carton and strips after EXP.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Telfast 180mg contains

The active substance of Telfast is fexofenadine hydrochloride. Each tablet contains 180mg of fexofenadine hydrochloride.

The other ingredients are:

Tablet core: microcrystalline cellulose,

pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

Film coating: hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Telfast 180 mg looks like and contents of the pack

Telfast 180 mg film-coated tablets are peach coloured, capsule shaped tablets marked with "018" on one side and "e" on the other.

Telfast is presented in over-labelled blister packs. Each tablet is blistered.

Telfast is available in packs of 30 tablets per package.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Telfast 180mg filmomhulde tabletten
Denmark: Telfast, filmovertrukne tabletter 180 mg
Finland: Telfast 180mg tabletti, kalvopäällysteinen
Germany: Telfast 180mg
Ireland: Telfast 180 mg film-coated tablets
Italy: Telfast 180 mg compresse rivestite con film
Portugal: Telfast 180, comprimidos revestidos por película
Spain: Telfast 180 mg comprimidos recubiertos con película
Sweden: Telfast 180 mg filmdragerade tabletter
United Kingdom: Telfast 180 mg film-coated tablets

Who has made your medicine?

Telfast 180mg is manufactured by Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37100 Tours, France

Procured from within the EU by the parallel product authorisation holder: McDowell Pharmaceuticals, 4 Altona Road, Lisburn, N. Ireland BT27 5QB, and repackaged by: Maxearn Limited, Lynstock House, Lynstock Way, Lostock, Bolton BL6 4SA, United Kingdom.

Date of leaflet preparation: JUNE 2013

Telfast and Zentiva are registered trademarks of Sanofi Aventis.

PARALLEL PRODUCT AUTHORISATION NUMBER: Telfast 180mg PPA 1473/52/1

REF: M1473/52/1/136

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Telfast 180 mg Film-coated tablets**

Fexofenadine hydrochloride

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1. What Telfast is and what it is used for

Telfast contains fexofenadine hydrochloride, which is an antihistamine.

Telfast 180 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. Before you take Telfast

 **Do not take Telfast**

X if you are allergic (hypersensitive) to fexofenadine or any of the other ingredients of Telfast (see section 6 for a full list of ingredients).

 **Take special care with Telfast**

- if you have problems with your liver or kidneys
- if you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- if you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Telfast.

 **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines,

including medicines obtained without a prescription.

Indigestion remedies containing aluminium and magnesium may affect the action of Telfast by lowering the amount of drug absorbed. It is recommended that you leave about 2 hours between the time that you take Telfast and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Telfast if you are pregnant, unless necessary.

Telfast is not recommended during breast feeding.



Driving and using machines

Telfast is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. How to take Telfast

Always take Telfast exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over

The recommended dose is one tablet (180 mg) daily.

Take your tablet with water before a meal.

If you take more Telfast than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Telfast

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Telfast

Tell your doctor if you want to stop taking Telfast before you have finished your course of treatment.

If you stop taking Telfast earlier than planned, your symptoms may return.



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

4. Possible side effects

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

Tell your doctor immediately and stop taking Telfast if you experience swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Common side effects (occurring in less than 1 in 10 but in more than 1 in 100 patients): headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but in more than 1 in 1,000 patients): tiredness/sleepiness.

Additional side effects (frequency unknown), which may occur are: difficulty sleeping (insomnia), sleeping disorders, bad dreams, nervousness, fast or irregular heart beat, diarrhoea, skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing.

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 Telfast

Keep out of the reach and sight of children.

Do not use Telfast after the expiry date which is stated on the over-labelled carton and strips after EXP.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Telfast 180mg contains

The active substance of Telfast is fexofenadine hydrochloride. Each tablet contains 180mg of fexofenadine hydrochloride.

The other ingredients are:

Tablet core: microcrystalline cellulose,

pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

Film coating: hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Telfast 180 mg looks like and contents of the pack

Telfast 180 mg film-coated tablets are peach coloured, capsule shaped tablets marked with "018" on one side and "e" on the other.

Telfast is presented in over-labelled blister packs. Each tablet is blistered.

Telfast is available in packs of 30 tablets per package.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Telfast 180mg filmomhulde tabletten

Denmark: Telfast, filmovertrukne tabletter 180 mg

Finland: Telfast 180mg tabletti, kalvopäällysteinen

Germany: Telfast 180mg

Ireland: Telfast 180 mg film-coated tablets

Italy: Telfast 180 mg compresse rivestite con film

Portugal: Telfast 180, comprimidos revestidos por película

Spain: Telfast 180 mg comprimidos recubiertos con película

Sweden: Telfast 180 mg filmdragerade tabletter

United Kingdom: Telfast 180 mg film-coated tablets

Who has made your medicine?

Telfast 180mg is manufactured by Sanofi

Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37100 Tours, France

Procured from within the EU by the parallel product authorisation holder: McDowell Pharmaceuticals, 4 Altona Road, Lisburn, N. Ireland BT27 5QB, and repackaged by: MPT Pharma Limited, Unit 43, Empire Industrial Park, Aldridge, Walsall WS9 8UG, United Kingdom.

Date of leaflet preparation: JUNE 2013

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PARALLEL PRODUCT AUTHORISATION NUMBER: Telfast 180mg PPA 1473/52/1

REF: MT1473/52/1/136

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Telfast 180 mg Film-coated tablets**

Fexofenadine hydrochloride

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- 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
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1. What Telfast is and what it is used for

Telfast contains fexofenadine hydrochloride, which is an antihistamine.

Telfast 180 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. Before you take Telfast

 **Do not take Telfast**

X if you are allergic (hypersensitive) to fexofenadine or any of the other ingredients of Telfast (see section 6 for a full list of ingredients).

 **Take special care with Telfast**

- if you have problems with your liver or kidneys
- if you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- if you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Telfast.

 **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines,

including medicines obtained without a prescription.

Indigestion remedies containing aluminium and magnesium may affect the action of Telfast by lowering the amount of drug absorbed. It is recommended that you leave about 2 hours between the time that you take Telfast and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Telfast if you are pregnant, unless necessary.

Telfast is not recommended during breast feeding.



Driving and using machines

Telfast is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. How to take Telfast

Always take Telfast exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over
The recommended dose is one tablet (180 mg) daily.

Take your tablet with water before a meal.

If you take more Telfast than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Telfast

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Telfast

Tell your doctor if you want to stop taking Telfast before you have finished your course of treatment.

If you stop taking Telfast earlier than planned, your symptoms may return.



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

4. Possible side effects

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

Tell your doctor immediately and stop taking Telfast if you experience swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Common side effects (occurring in less than 1 in 10 but in more than 1 in 100 patients):
headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but in more than 1 in 1,000 patients):
tiredness/sleepiness.

Additional side effects (frequency unknown), which may occur are: difficulty sleeping (insomnia), sleeping disorders, bad dreams, nervousness, fast or irregular heart beat, diarrhoea, skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing.

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 Telfast

Keep out of the reach and sight of children.

Do not use Telfast after the expiry date which is stated on the over-labelled carton and strips after EXP.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Telfast 180mg contains

The active substance of Telfast is fexofenadine hydrochloride. Each tablet contains 180mg of fexofenadine hydrochloride.

The other ingredients are:

Tablet core: microcrystalline cellulose,

pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

Film coating: hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

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Ireland: Telfast 180 mg film-coated tablets
Italy: Telfast 180 mg compresse rivestite con film
Portugal: Telfast 180, comprimidos revestidos por película
Spain: Telfast 180 mg comprimidos recubiertos con película
Sweden: Telfast 180 mg filmdragerade tabletter
United Kingdom: Telfast 180 mg film-coated tablets

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Procured from within the EU by the parallel product authorisation holder: McDowell Pharmaceuticals, 4 Altona Road, Lisburn, N. Ireland BT27 5QB, and repackaged by: NG Limited, Units 8-12, Cornwall Road Industrial Estate, Smetwick, West Midlands B66 2JT, United Kingdom.

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