



Package leaflet: Information for the user

Escitalopram Actavis 5 mg Film-coated Tablets

Escitalopram Actavis 10 mg Film-coated Tablets

Escitalopram Actavis 15 mg Film-coated Tablets

Escitalopram Actavis 20 mg Film-coated Tablets

Escitalopram

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 What Escitalopram Actavis is and what it is used for
- 2 What you need to know before you take Escitalopram Actavis
- 3 How to take Escitalopram Actavis
- 4 Possible side effects
- 5 How to store Escitalopram Actavis
- 6 Contents of the pack and other information

1 What Escitalopram Actavis is and what it is used for

Escitalopram Actavis is an antidepressant which belongs to the 'SSRI' group (selective serotonin reuptake inhibitors). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

- Escitalopram Actavis is used to treat:
- Depressive disorders (episodes of a major depression)
 - Panic disorder with or without agoraphobia (e.g. fear of leaving the house, entering shops, being in crowds and in public places)
 - Social anxiety disorder (social phobia)
 - Generalised anxiety disorder
 - Obsessive-compulsive disorder

2 What you need to know before you take Escitalopram Actavis

Do not take Escitalopram Actavis

- if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6)
- if you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic)
- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "Other medicines and Escitalopram Actavis")

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before taking Escitalopram Actavis
- Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:
- if you have epilepsy. Treatment with Escitalopram Actavis should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section 4 "Possible side effects")
 - if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage
 - if you have diabetes. Treatment with Escitalopram Actavis may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted
 - if you have a decreased level of sodium in the blood
 - if you have low levels of potassium or magnesium in your blood (hypokalaemia / hypomagnesaemia)
 - if you have a tendency to easily develop bleeding or bruises
 - if you are receiving electroconvulsive treatment
 - If you have coronary heart disease
 - if you suffer or have suffered from heart problems or have recently had a heart attack
 - if you suffer from a heart condition called 'QT-prolongation' or if the condition runs in your family

- if you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate
- if you have or have a history of glaucoma

Please note

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

Escitalopram Actavis should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Escitalopram Actavis for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Escitalopram Actavis for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Escitalopram Actavis. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Escitalopram Actavis in this age group have not yet been demonstrated.

Other medicines and Escitalopram Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

DO NOT TAKE Escitalopram Actavis if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparflaxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

- Tell your doctor if you are taking any of the following medicines:
- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Escitalopram Actavis. After stopping Escitalopram Actavis you must allow 7 days before taking any of these medicines.
 - "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
 - "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
 - The antibiotic linezolid.
 - Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
 - Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.

- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Escitalopram Actavis.
- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression.
- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anti-coagulant).
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anti-coagulant). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Escitalopram Actavis in order to verify that your dose of anti-coagulant is still adequate.
- Mefloquin (used to treat Malaria), bupropion (used to treat depression and to help you quit smoking) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) due to a possible risk of a lowered threshold for seizures, and antidepressants.
- Flecainide, propafenone, and metoprolol (used in cardio-vascular diseases), desipramine, clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Escitalopram Actavis may need to be adjusted.
- Medicines that prolong the so-called 'QT interval' or medicines which lower potassium or magnesium levels in the blood. Ask your doctor for advice on these medicines.

Escitalopram Actavis with food, drink and alcohol

Escitalopram Actavis can be taken with or without food (see section 3 "How to take Escitalopram Actavis").

As with many medicines, combining Escitalopram Actavis with alcohol is not advisable, although Escitalopram Actavis is not expected to interact with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Make sure your midwife and/or doctor know you are on Escitalopram Actavis. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalopram Actavis may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or your doctor immediately.

If you take Escitalopram Actavis during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.

If used during pregnancy Escitalopram Actavis should never be stopped abruptly.

Do not take Escitalopram Actavis if you are breast-feeding unless you and your doctor have discussed the risks and benefits involved. Ask your doctor or pharmacist for advice before taking any medicine.

Fertility

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines

This medicine can alter reaction times severely enough, even when used as indicated, to impair the ability to drive or use machinery. Do not drive a car or operate machinery until you know how Escitalopram Actavis affects you.


3 How to take Escitalopram Actavis

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

To treat depression
The recommended dose of Escitalopram Actavis is 10 mg taken as one daily dose. The dose can be increased by your doctor to a maximum of 20 mg per day.

AAA1072

Escitalopram 5mg, 10mg, 15mg, 20mg film-coated tablets PIL for Blisters - Ireland			
 @ awstudio@actavis.co.uk	item no:	AAA1072	dimensions: 190/380 mm
	print proof no:	4	pharmacode:
	origination date:	17.06.16	min pt size: 7.75pt
	originated by:	DR	
	revision date:	20.09.16	
	revised by:	DR	
approved for print/date	supplier:	Malta Zejtun	
Technical Approval			
date sent: N/A			
technically app. date*: N/A			
colours/plates:			
1. black			
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Non Printing Colours			
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To treat panic disorders, with or without agoraphobia
The starting dose of Escitalopram Actavis is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

To treat social anxiety disorder (social phobia)
The recommended dose of Escitalopram Actavis is 10 mg taken as one daily dose. Depending on your response to the treatment, your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg daily.

To treat generalised anxiety disorder
The normally recommended dose of Escitalopram Actavis is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

To treat Obsessive-Compulsive Disorder (OCD)
The recommended dose of Escitalopram Actavis is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg daily. For long-term treatment, the benefits of treatment should be regularly checked.

Elderly patients (above 65 years of age)
The recommended starting dose of Escitalopram Actavis is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day. The efficacy of Escitalopram Actavis in social anxiety disorder (social phobia) in elderly patients has not been studied.

Patients with impaired liver function
The recommended starting dose of Escitalopram Actavis for patients with impaired liver function should not exceed 5 mg daily in the first 14 days. Your doctor can then raise the daily dose, depending on your response, up to 10 mg daily. Caution and an especially careful dose titration are indicated in patients with severely impaired liver function.

Patients with impaired kidney function
With mild to moderate impairment of kidney function, no dose adjustment is required. Caution is indicated for patients with severely impaired kidney function.

Use in children and adolescents (below 18 years of age)
Escitalopram Actavis should not normally be given to children and adolescents. For further information please see section 2 "What you need to know before you take Escitalopram Actavis".

Escitalopram Actavis 5 mg film-coated tablets:
Please take the film-coated tablets once daily, swallowed whole with sufficient fluid (preferably a glass of water). Escitalopram Actavis may be taken with or without food.

Escitalopram Actavis 10, 15 and 20 mg film-coated tablets:
Please take the film-coated tablets once daily, swallowed whole with sufficient fluid (preferably a glass of water). Escitalopram Actavis may be taken with or without food. If necessary, tablets may be broken by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.



Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Escitalopram Actavis even if it takes some time before you feel any improvement in your condition. Do not change the dose of your medicine without talking to your doctor first. Continue to take Escitalopram Actavis for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you take more Escitalopram Actavis than you should
If you have taken more Escitalopram Actavis than you should, or if someone else has taken your medicine by mistake, inform your doctor or go to a hospital straight away. Do this even if you still feel well. Take any remaining tablets as well as the box/container with you, even if this is empty. Symptoms of overdose might include dizziness, shaking, restlessness, feeling sleepy, falling unconscious, change in heart rhythm, fits, hypoventilation, muscle weakness, tenderness or pain and feeling unwell or have a high temperature (rhabdomyolysis), change in body fluid/salt balance, vomiting and being sick.

If you forget to take Escitalopram Actavis
Do not take a double dose to make up for forgotten doses. If you should forget to take a dose of Escitalopram Actavis, just take Escitalopram Actavis as usual the next time.

If you stop taking Escitalopram Actavis
If you want to interrupt the treatment, please discuss this with your doctor beforehand. He might need to take appropriate measures. Do not stop taking the medicine on your own initiative without discussing this with your doctor. When stopping treatment with Escitalopram Actavis, your doctor will gradually reduce your dose over a number of weeks or months. This should help reduce the possibility of withdrawal effects.

When you stop taking Escitalopram Actavis, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalopram Actavis is stopped. The risk is higher, when Escitalopram Actavis has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Escitalopram Actavis, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea) and vomiting, sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

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

4 Possible side effects

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

Side effects most commonly occur in the first or second week of treatment, and normally become less severe and less frequent as treatment continues.

See your doctor if you get any of the following side effects during treatment:

- Uncommon (more than 1 out of 1000 persons and less than 1 out of 100 persons):
- Unusual bleeds, including gastrointestinal bleeds
- Rare (more than 1 out of 10000 and less than 1 out of 1000 persons):
- If you experience swelling of the skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), contact your doctor or go to a hospital straight away.
 - If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

If you experience the following side effects you should contact your doctor or go to the hospital straight away:

- Difficulties urinating
- Seizures (fits)
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes

In addition to above the following side effects have been reported:

- Very common (more than 1 out of 10 persons):
- Feeling sick (nausea)
 - Headache

- Common (more than 1 out of 100 persons and less than 1 out of 10 persons):
- Generalised fear, restlessness, abnormal dreams, difficulty in sleeping, sleepiness, dizziness, a skin sensation, such as burning, prickling, itching, or tingling, with no apparent physical cause, tremor, yawning
 - Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
 - Diarrhoea, constipation, vomiting, dry mouth
 - Blocked or runny nose (sinusitis)
 - Increased sweating
 - Fatigue, fever
 - Joint and muscle pain
 - Increased weight
 - Decreased or increased appetite

- Uncommon (more than 1 out of 1000 persons and less than 1 out of 100 persons):
- Involuntary grinding or clenching of the teeth, agitation, nervousness, panic attack, confusion state
 - Taste disturbance, sleep disorder, fainting
 - Nosebleed
 - Bleeding from the uterus that is not associated with menstruation, abnormally heavy or extended menstrual flow
 - Nettle rash (urticaria), rash, itching (pruritus)
 - Hair loss
 - Swelling of the arms or legs
 - Enlarged pupils (mydriasis), blurred vision, ringing in the ears (tinnitus)
 - Fast heart beat
 - Decreased weight

- Rare (more than 1 out of 10000 and less than 1 out of 1000 persons):
- Aggression, depersonalisation, hallucination
 - Slow heart beat

- Some patients have reported (frequency cannot be estimated from the available data):
- Thoughts of harming yourself or thoughts of killing yourself, see also section "Warnings and precautions"
 - Mania
 - Movement disorders (involuntary movements of the muscles)
 - Flow of milk in women that are not nursing
 - Painful erection of the penis
 - Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia)
 - Dizziness when you stand up due to low blood pressure (orthostatic hypotension)

- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Abnormal liver function test (increased amounts of liver enzymes in the blood)
- Sudden swelling of the skin and mucosa (angioedemas)
- Suicide-related events
- Inability to sit still or remain motionless, feeling of restlessness associated with increased movement*
- Anorexia*
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)

*These side effects have been reported with drugs that work in a similar way to escitalopram (the active ingredient of Escitalopram Actavis).

An increased risk of bone fractures has been observed in patients taking this type of medicine.

Reporting of side effects

If you get any side effect, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Escitalopram Actavis

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister strips, tablet container and carton after EXP. The expiry date refers to the last day of that month.

Blister packs: Do not store above 25°C
Tablet container: Do not store above 30°C

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Escitalopram Actavis contains:
The active substance is escitalopram. Each film-coated tablet contains 5 mg, 10 mg, 15 mg or 20 mg escitalopram (as oxalate). The other ingredients are: *tablet core*: microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, talc, magnesium stearate, *coating*: hypromellose 6cP, titanium dioxide (E 171), macrogol 6000.

What Escitalopram Actavis looks like and contents of the pack:

Escitalopram Actavis 5 mg: Round, biconvex, white film-coated tablets (diameter 6 mm), marked with 'E' on one side.
Escitalopram Actavis 10 mg: Oval, biconvex, white film-coated tablets, (6.4 mm x 9.25 mm), with score on one side, sidescores and marked with 'E' on the other side. The tablet can be divided into equal halves.
Escitalopram Actavis 15 mg: Oval, biconvex, white film-coated tablets, (7.3 mm x 10.6 mm), with score on one side, sidescores and marked with 'E-' on the other side. The tablet can be divided into equal halves.
Escitalopram Actavis 20 mg: Oval, biconvex, white film-coated tablets, (8 mm x 11.7 mm), with score on one side, sidescores and marked with 'E' on the other side. The tablet can be divided into equal halves.

Escitalopram Actavis is obtainable in blister packs of 14, 20, 28, 30, 50, 56, 60, 98, 100 and 200 tablets, and tablet containers of 100 tablets and 200 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder:
Actavis Group PTC ehf, Reykjavikurvegi 76-78
220 Hafnarfjörður, Iceland

Manufacturers:
Actavis Limited, BLB016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

Actavis ehf, Reykjavikurvegur 78,
220 Hafnarfjörður, Iceland

Balkanpharma Dupnitsa AD,
3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria

Tjoapack Netherlands B.V.
Nieuwe Donk 9, 4879 AC Etten-Leur, Netherlands

Actavis Group PTC ehf,
Reykjavikurvegur 76-78, IS-220 Hafnarfjörður, Iceland



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

Denmark:	Escitalopram Actavis Filmovertrukne tabletter 5 mg, 10 mg, 15 mg og 20 mg
Estonia:	Escitalopram Actavis
Greece:	Escitalopram / Actavis
Spain:	Escitalopram Aurovitas Spain 10 mg, 15 mg & 20 mg comprimidos recubiertos con película
Finland:	Escitalopram Actavis 5 mg, 10 mg, 15 mg & 20 mg tabletti, kalvopäällysteinen
Ireland:	Escitalopram Actavis 5 mg, 10 mg, 15 mg & 20 mg Film-coated Tablets
Iceland	Esopram , 5 mg, 10 mg, 15 mg & 20 mg filmuhúðaðar töflur
Lithuania	Escitalopram Actavis
Latvia:	Escitalopram Actavis
Norway:	Escitalopram Actavis
Poland:	Escitalopram Actavis

This leaflet was last revised in August 2016.



AAAJ1072

Escitalopram 5mg, 10mg, 15mg, 20mg film-coated tablets PIL for Blisters - Ireland				colours/plates:	
 creating value in pharmaceuticals @ awstudio@actavis.co.uk		item no:	AAAJ1072	dimensions:	190/380 mm
		print proof no:	4	pharmacode:	
		origination date:	17.06.16	min pt size:	7.75pt
		originated by:	DR		
		revision date:	20.09.16		
<div>approved for print/date</div>		revised by:	DR		
		supplier:	Malta Zejtun		
				Technical Approval	
				date sent:	N/A
				technically app. date*:	N/A
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