Tarivid® 200 mg

film-coated tablets

Active substance: ofloxacin

sanofi aventis

In this leaflet:

Tarivid® 200 mg film-coated tablets

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1. WHAT TARIVID 200 MG FILM-COATED TABLETS ARE AND WHAT IT IS USED FOR

1.1 Tarivid 200 mg film-coated tablets are a bactericidal (bacteria-killing) antibiotic/chemotherapeutic agent with a broad spectrum of activity belonging to the fluoroquinolone family.

1.2 Tarivid 200 mg film-coated tablets are suitable for the treatment of the following bacterial infections if they are due to ofloxacin-susceptible micro-organisms:

− Acute, chronic and recurrent infections of the respiratory tract (bronchitis) caused by *Haemophilus influenzae* or other Gram-negative and multiresistant micro-organisms and to *Staphylococcus aureus*.

− Inflammation of the lungs (pneumonia), due in particular to problem organisms such as *Escherichia coli*, *Klebsiella*, *Enterobacter*, *Proteus*, *Pseudomonas*, *Legionella*, *Staphylococcus*. Because community-acquired pneumonia (i.e. acquired outside the hospital) is predominantly due to pneumococci, Tarivid 200 mg film-coated tablets are not the first choice treatment in these cases.

− Chronic and recurrent infections of the ear, nose and throat, particularly due to Gram-negative organisms including *Pseudomonas* or *Staphylococcus*. Tarivid 200 mg film-coated tablets should therefore not be used for the treatment of acute tonsillitis (angina tonsillaris) due to beta-haemolytic streptococci (also see 3.2 under "Duration of treatment").

− Skin and soft tissue infections.

− Bone infections (osteitis, osteomyelitis).

− Infections of the abdominal cavity, including the true pelvis, and bacteria-induced diarrhoea requiring antibiotic treatment.

− Infections of the kidneys, urinary tract (renal pelvis, ureters, bladder, urethra) and sex organs; gonorrhoea.

Tarivid 200 mg film-coated tablets can also be taken to prevent infections (infection prophylaxis, also by selective intestinal decontamination) in patients with clearly weakened immune systems (e.g. patients with neutropenia).

Ofloxacin is not active against *Treponema pallidum* (causative micro-organism of syphilis).

2. BEFORE YOU TAKE TARIVID® 200 MG FILM-COATED TABLETS

2.1 **Do not take Tarivid 200 mg film-coated tablets**

− if you are hypersensitive (allergic) to ofloxacin, the active substance of Tarivid 200 mg film-coated tablets, other quinolones (i.e. medicines from the same chemical group of substances as ofloxacin) or any of the other ingredients of Tarivid 200 mg film-coated tablets. The reason for this is the risk of a hypersensitivity reaction,

− if you suffer from epilepsy (fits) or you know that you have a tendency to seizures (lowered seizure threshold) as a result of brain damage (e.g. from injuries, inflammation or stroke). The reason for this is the risk of triggering seizures,

− if you have suffered tendon disorders at any time after the use of quinolones. The reason for this is the risk of tendon rupture,

− for children and adolescents up to the age of 18, as damage to the joint cartilage cannot be definitely ruled out,

− during pregnancy,

− if you are breast-feeding.

2.2 **Take special care with Tarivid 200 mg film-coated tablets**

− if, following treatment with other quinolones, you have previously suffered severe adverse effects (e.g. severe nervous system reactions), you may also be at increased risk of suffering similar reactions to Tarivid 200 mg film-coated tablets.

− if you are susceptible to seizures. If so, as with other quinolones Tarivid 200 mg film-coated tablets should only be used with extreme caution. This applies if for example you have brain damage, if you are taking certain drugs for rheumatic disorders and pain (fenbufen or similar non-steroidal anti-inflammatory drugs) at the same time or are being treated with drugs that lower the seizure threshold, such as theophylline (also see Section 2.3 "Taking other medicines").

− if you develop severe, persistent and/or bloody diarrhoea. These symptoms during or in the first few weeks after treatment with various antibiotics (particularly broad spectrum antibiotics) can be a sign of a bowel inflammation induced by the bacterium *Clostridium difficile*, the most serious form of which is pseudomembranous colitis (see Section 4.1 and 4.2).

− if you develop tendon disorders (e.g. pain). These symptoms can indicate tendinitis (inflammation of the tendons) which is rarely observed during treatment with quinolones. This can lead to rupture, particularly of the Achilles tendon. Elderly patients are more prone to tendinitis. The risk of tendon rupture appears to be increased by treatment with corticosteroids ("cortisone products"). If tendinitis is suspected, medical advice should be sought immediately and the affected tendon treated accordingly, particularly by immobilisation. Treatment with Tarivid 200 mg film-coated tablets should be stopped following discussion with the doctor. Also see Sections 2.1 and 4.1 in this respect.

− if your kidney function is impaired, ofloxacin should only be used after adjustment of the dose and under medical supervision of your kidney function.

− if you observe symptoms such as fungal infestation of the mucous membranes, with reddening and whitish patches of the mucous membranes. Particularly, prolonged use of antibiotics can result in proliferation of micro-organisms which are non-susceptible to the drugs used, such as Tarivid 200 mg film-coated tablets. These symptoms can be signs of a possible secondary infection with these micro-organisms. Secondary infections must be treated accordingly.

− since photosensitisation (damage to the skin by light) can occur when using Tarivid 200 mg film-coated tablets, it is recommended that you do not expose yourself unnecessarily to strong sunlight or artificial UV radiation (e.g. UV lamp, solarium) so as to avoid photosensitisation.

− if you have a hereditary metabolic disorder of the red blood cells (glucose-6-phosphate dehydrogenase deficiency) or a family history of this disorder, ofloxacin can cause reactions which result in the destruction of the red blood cells (haemolysis).

− use of Tarivid 200 mg film-coated tablets can cause liver damage. If you suffer from impaired liver function, ofloxacin should only be used under medical supervision of your liver function.

− laboratory determinations of opiates or porphyrin (constituent and degradation product of the red blood pigment) in the urine may yield false-positive results during treatment with Tarivid 200 mg film-coated tablets.

a) **Pregnancy and breast feeding**

Ofloxacin should not be administered to pregnant or breast-feeding women since there is insufficient experience on its safety in these patients.

Ofloxacin crosses the placenta and, in the amniotic fluid, reaches about 30% of the maximum concentration measured in the maternal serum.

Animal studies with ofloxacin have shown that damage to the joint cartilage cannot be completely ruled out in the growing body.

b) **Driving and using machines**

Some side effects such as dizziness or drowsiness (see under "Possible side effects") can affect your ability to concentrate and react. This may constitute a risk in situations where these abilities are of particular importance (e.g. driving a car or operating machinery). Alcohol consumption increases this risk.

c) **Important information about some of the ingredients of Tarivid 200 mg film-coated tablets**

This medicinal product contains lactose. Therefore, if you know that you suffer from intolerance to certain sugars, only take Tarivid 200 mg film-coated tablets after consulting your doctor.

2.3 **Taking other medicines**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even over-the-counter medications.

The effectiveness of Tarivid 200 mg film-coated tablets may be reduced when the drug is given in combination with medications used to lower stomach acidity (mineral antacids) or to protect the stomach lining (e.g. sucralfate). This is also the case with other medicines containing specific metal ions (aluminium, iron, magnesium or zinc). If you are taking this type of medication, please pay attention to the instructions in Section 3.1.

There is evidence that epileptic fits are more likely to occur if other drugs that lower the seizure threshold are given at the same time as quinolones. These include for example many agents for rheumatic disorders and pain (non-steroidal anti-inflammatory drugs, e.g. fenbufen) or the anti-asthma agent, theophylline. Theophylline concentrations in the blood, however, are not appreciably affected by ofloxacin. When taken at the same time as these agents, ofloxacin should only be used with great caution (also see Section 2.2 "Take special care with Tarivid 200 mg film-coated tablets“).

Quinolones and other drugs - e.g. probenecid (anti-gout agent), cimetidine (agent against gastric acid), furosemide (agent to promote the excretion of urine) or methotrexate (agent for the treatment of tumours, rheumatism for instance), which are eliminated in a particular way by the kidney (tubular secretion) - can mutually interfere with drug excretion, particularly when used at high doses. This can result in accumulation of these substances in the body and increased side effects.

Quinolones, and possibly ofloxacin as well, can increase the effect of coumarin derivatives (products which inhibit blood coagulation). It is therefore recommended that the blood clotting ability of patients treated simultaneously with coumarin derivatives be carefully monitored.

Ofloxacin can cause a slight increase in glibenclamide blood levels (product to counteract increased blood sugar). Since this may lead to low blood sugar levels, particularly close blood sugar monitoring is recommended in such cases.

3. HOW TO TAKE TARIVID 200 MG FILM-COATED TABLETS

Always take Tarivid 200 mg film-coated tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

3.1 The Tarivid 200 mg film-coated tablets dosage is based on the type and severity of your disease. Your doctor will inform you how to take Tarivid 200 mg film-coated tablets. The following data may serve as a recommendation for your doctor:

Indications	**Unit and daily doses**
Uncomplicated lower urinary tract infections	2 x 100 mg ofloxacin daily, i.e. 2 x ½ Tarivid 200 mg film -coated tablet
Uncomplicated gonorrhoea	1 x 400 mg ofloxacin as a single dose, i.e. 1 x 2 Tarivid 200 mg film-coated tablets
Infections of the kidneys, urinary tract and sex organs	2 x 200 mg ofloxacin daily, i.e. 2 x 1 Tarivid 200 mg film-coated tablets
Airways and ear, nose and throat infections	2 x 200 mg ofloxacin daily, i.e. 2 x 1 Tarivid 200 mg film-coated tablets
Skin and soft tissue infections	2 x 200 mg ofloxacin daily, i.e. 2 x 1 Tarivid 200 mg film-coated tablets
Bone infections	2 x 200 mg ofloxacin daily, i.e. 2 x 1 Tarivid 200 mg film-coated tablets
Infections of the abdominal cavity (including bacteria-induced diarrhoea)	2 x 200 mg ofloxacin daily, i.e. 2 x 1 Tarivid 200 mg film-coated tablets

In individual cases, it may be necessary to increase the dose for micro-organisms with variable susceptibility, in severe infections (e.g. of the airways or bones) or if your response to treatment is insufficient. In these cases, the dose can be increased to 2 x 400 mg ofloxacin daily (i.e. 2 x 2 Tarivid 200 mg film-coated tablets). This also applies to infections with complications.

For prevention of infections in patients with clearly weakened immune systems the recommended daily dose of ofloxacin is 400 to 600 mg (i.e. 2 to 3 Tarivid 200 mg film-coated tablets).

Dosage in patients with impaired kidney function

In patients with moderate and severe impairment of kidney function, which is determined by elimination of creatinine from blood (creatinine clearance) or the creatinine content in blood (serum creatinine), the following dosage is recommended:

The first dose is the same as that in patients with normal kidney function, depending on the type and severity of the disease. Treatment is then given at lower doses or with longer intervals between individual doses. The information below serves as a guideline to your doctor for the continuation of therapy (maintenance dose).

Creatinine clearance	**Serum creatinine (creatinine content in blood)**	**Maintenance dose**
50 to 20 ml/min	1.5 to 5 mg/dl	100 mg to 200 mg ofloxacin, i.e. ½ to 1 Tarivid 200 mg film-coated tablet daily
Less than 20 ml/min	More than 5 mg/dl	100 mg of ofloxacin, i.e. ½ Tarivid 200 mg film-coated tablet daily
Haemodialysis or peritoneal dialysis		100 mg ofloxacin, i.e. ½ Tarivid 200 mg film-coated tablet daily

In individual cases (see above), it may be necessary to increase the dose.

Dosage in patients with impaired liver function

In patients with severely impaired liver function (e.g. in cirrhosis of the liver with ascites), ofloxacin excretion may be reduced. It is therefore recommended that a maximum daily dose of 400 mg of ofloxacin should not be exceeded in these patients, i.e. 2 Tarivid 200 mg film-coated tablets.

3.2 Tarivid 200 mg film-coated tablets should be taken unchewed with sufficient liquid (½ to 1 glass). The tablets can be taken both on an empty stomach and at meal times.

The effectiveness of Tarivid 200 mg film-coated tablets may be reduced when the drug is given in combination with medications used to lower stomach acidity or to protect the stomach lining. This is also the case with other medicines containing specific metal ions (aluminium, iron, magnesium or zinc). Tarivid 200 mg film-coated tablets should therefore be taken about 2 hours before these types of medications (see also Section 2.3. “Taking other medicines”).

Up to 400 mg of ofloxacin can be given as a single dose. The total daily dose should be divided into a morning and an evening dose. It is important that the intervals between doses of Tarivid 200 mg film-coated tablets should be approximately the same. Single doses of up to 400 mg of ofloxacin per day (e.g. for the treatment of gonorrhoea) should preferably be taken in the morning.

3.3 The duration of treatment is based on the response of the micro-organism and your state of health.

In principle, it is recommended that treatment should be continued for at least 3 days after the fever has abated and the signs of the disease have subsided.

In acute infections, treatment for 7 to 10 days is usually sufficient. In infections due to *Salmonella* (micro-organism causing bowel infections for instance), the normal treatment duration is 7 to 8 days, while in infections caused by *Shigella* (micro-organism causing dysentery) it is 3 to 5 days and in bowel infections due to *Escherichia coli* (bowel organism) it is 3 days.

For treatment of uncomplicated gonorrhoea a single dose of 400 mg of oxfloxacin is sufficient.

For uncomplicated infections of the lower urinary tract, a treatment duration of 3 days is usually sufficient.

In bone infections, the duration of treatment is 3 to 4 weeks, or longer in isolated cases.

If infections due to beta-haemolytic streptococci (e.g. erysipelas) of known sensitivity are to be treated, treatment must be given for at least 10 days to prevent secondary damage, such as rheumatic fever or kidney inflammation (glomerulonephritis). However, since beta-haemolytic streptococci have variable sensitivity to ofloxacin, treatment of these infections requires demonstration of sensitivity in individual cases.

Until further information is available, it is recommended that a treatment duration of 2 months should not be exceeded.

3.4 **If you take more Tarivid 200 mg film-coated tablets than you should.**

If an excessive amount of ofloxacin is used, signs of nervous system disturbances may occur, such as confusion, dizziness, reduction of consciousness and seizures, as well as disorders of the gastro-intestinal region such as nausea and damage (erosion) of the gastro-intestinal mucous membranes. These disorders require medical supervision and sometimes immediate countermeasures.

If you have only taken double the intended dose, it is enough to ask a doctor for advice if you observe any side effects. Continue your Tarivid 200 mg film-coated tablet treatment as planned.

If by mistake you have taken more than twice as many Tarivid 200 mg film-coated tablets as you should, please consult a doctor immediately so that he/she can give you advice or if necessary, monitor you or provide treatment.

The elimination of ofloxacin can be increased by forced diuresis (higher excretion of urine).

3.5 **If you forget to take Tarivid 200 mg film-coated tablets:**

A skipped dose must be given as soon as possible and treatment then continued as originally planned; however, the permitted daily dose should not be exceeded. Ask a doctor for advice if you are in doubt.

3.6 **Effects when treatment with Tarivid 200 mg film-coated tablets is stopped:**

Irregular doses, single or daily doses that are too low, and a treatment duration that is too short can negatively affect the treatment's success.

If you have any other questions about the use of the drug, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tarivid 200 mg film-coated tablets can have side effects.

In assessing side effects, the following frequency rates are used:

Very Common: More than 1 in 10 treated patients	**Common:** Fewer than 1 in 10, but more than 1 in 100 treated patients
Uncommon: Fewer than 1 in 100, but more than 1 in 1000 treated patients	**Rare:** Fewer than 1 in 1000, but more than 1 in 10 000 treated patients
Very rare: 1 case or fewer in 10 000 treated patients including isolated cases	

4.1 Medicines can also have unwanted effects, known as side effects. However, these do not occur in all patients. Information on known adverse effects of Tarivid 200 mg film-coated tablets is given below:

Infections and parasitic diseases

Uncommon: secondary infections due to non-sensitive micro-organisms (bacteria, fungi). (Also see Section 2.2 "Take special care with Tarivid 200 mg film-coated tablets")

Blood and lymphatic system disorders

Very rare: deficiency of certain blood cells (anaemia, leucopenia, thrombocytopenia, agranulocytosis or pancytopenia), destruction of red blood cells (haemolytic anaemia), increase in the number of certain white blood cells (eosinophilia), serious disorders of blood cell formation (bone marrow depression).

Signs of these blood disorders may be:

− pallor and weakness, red-coloured urine,

− inflammatory changes of mucous membranes (e.g. in the mouth and throat, anal and genital regions), sore throat and unexpectedly prolonged or recurrent fever or,

− increased bleeding tendency (e.g. increased tendency to bruising) and the increased occurrence of "petechiae" (small, pinpoint, reddish spots on the skin and mucous membranes).

Immune system disorders

Uncommon: signs of hypersensitivity reactions such as itching, rash, burning eyes, conjunctivitis, throat irritation and running nose.

Rare: hypersensitivity reactions such as nettle rash, swelling of the skin and mucous membranes, e.g. of the face, tongue and in the area of the throat (angio-oedema), breathlessness/spasm of the airways, blister-like or pustular rash.

Very rare: inflammation of small blood vessels (vasculitis) with pinpoint bleeding (petechiae), small blisters or nodules which in individual cases may lead to skin damage or even skin cell death and can also involve internal organs. Rash recurring at the same site (fixed drug eruption), serious hypersensitivity reactions (anaphylactic/anaphylactoid shock, severe breathlessness), serious skin and mucous membrane reactions, sometimes with blister formation and detachment of the skin (erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome), allergic inflammation of the lungs (pneumonitis).

Metabolic and nutritional disorders

Very rare: rise or fall in blood sugar, particularly in patients treated with blood sugar-lowering agents, attacks of porphyria in patients with porphyria (a rare metabolic disorder).

Psychiatric disorders

Uncommon: confusion.

Rare: psychotic reactions with hallucinations, agitation, anxiety, vivid dreams (even night-mares), depression.

Very rare: psychotic reactions and depression with self-endangering behaviour, even suicidal thoughts or acts. Such reactions can occur even after first-time use. Tarivid 200 mg film-coated tablets must then be stopped immediately.

Nervous system disorders

Uncommon: agitation, nervousness, dizziness, headache, sleep disturbances.

Rare: drowsiness, sensory disturbances such as abnormal sensations (e.g. tingling, sensation of numbness), hyper- or hypo-aesthesia (increased or reduced perception of touch stimuli), taste and smell disturbances (even loss of the sense of taste or smell), visual disorders (such as blurred vision, double vision and altered colour vision), balance disorders, hearing disorders and ringing in the ears (tinnitus), seizures, extrapyramidal symptoms (e.g. increased or reduced muscle tension, involuntary movements of the face or body, delayed start of movement, lack of movement) or muscle co-ordination disorders (e.g. trembling, unsteady walk).

Very rare: hearing loss.

Heart disorders

Uncommon: accelerated pulse rate (tachycardia), palpitations.

Certain heart rhythm disorders have been observed very rarely (e.g. ventricular tachycardia, torsades de pointes), as well as momentary loss of consciousness (syncope). Patients with existing abnormal electrocardiogram (ECG, prolonged QT interval), abnormal blood mineral balance (such as hypokalaemia) and those taking other medicines which can also cause heart rhythm disorders at the same time, are at particular risk.

Vascular disorders

Uncommon: drop in blood pressure (very rarely progressing to circulatory collapse with loss of consciousness).

Rare: hot flushes, increase in blood pressure.

Gastro-intestinal disorders

Common: loss of appetite, stomach disorders, abdominal pain, digestion problems (dyspepsia), diarrhoea, nausea, vomiting.

Rare: inflammation of the bowel (enterocolitis, in isolated cases also with blood in the stools), pseudomembranous colitis (serious bowel inflammation, also see Section 2.2 "Take special care with Tarivid 200 mg film-coated tablets" and Section 4.2 "Countermeasures to be taken in the event of side effects").

Liver and bile disorders

Rare: impairment of liver function with an increase in liver enzymes and/or bilirubin (bile pigment in the blood).

Very rare: jaundice as a result of reduced elimination of the bile pigment (cholestatic jaundice), inflammation of the liver (hepatitis), severe liver damage.

Disorders of the skin and subcutaneous cell tissue

Rare: sweating.

Very rare: hypersensitivity of the skin to light (e.g. sunburn-like reactions, discolouration or detachment of the nails).

Skeletal muscle, connective tissue and bone disorders

Rare: tendon disorders (e.g. pain, inflammation of the tendon).

Very rare: tendon rupture (e.g. Achilles tendon rupture). As with other fluoroquinolones, this may occur within 48 hours of the beginning of treatment and may affect both heels (also see Section 2.2 "Take special care with Tarivid 200 mg film-coated tablets"). Joint and muscle symptoms (e.g. pain), damage to the muscle tissue (rhabdomyolysis), muscle weakness (may be of special importance in patients with myasthenia gravis, a severe muscle disease, for example).

Disorders of the kidneys and urinary tract

Rare: impairment of kidney function (this is shown for example by increased serum creatinine).

Very rare: acute kidney failure (signs of this may be a marked increase and decrease in urine excretion associated with a general feeling of illness), acute interstitial nephritis (allergic inflammation of the kidneys).

General disorders and symptoms at the administration site

Very rare: fever.

Note

Apart from very rare cases (individual cases of smell, taste and hearing disorders for example), the adverse effects observed have disappeared after stopping Tarivid 200 mg film-coated tablets.

4.2 **Countermeasures to be taken in the event of side effects**

The following side-effects (for further details of these side-effects, see above) can sometimes be life-threatening. In these cases, a doctor must be informed immediately if such an event occurs suddenly or becomes intense.

Pseudomembranous colitis (severe bowel disease):

In this case (even if only suspected), the doctor must consider stopping treatment with Tarivid 200 mg film-coated tablets depending on the indication and, where necessary, institute appropriate treatment immediately (e.g. administration of special antibiotics/chemotherapeutic agents with proven clinical efficacy). Drugs that inhibit bowel movement (peristalsis) should not be used.

Severe acute hypersensitivity reactions (e.g. anaphylaxis):

These can occur even on first-time use and develop rapidly (i.e. within minutes or hours after administration). In this case, treatment with Tarivid 200 mg film-coated tablets must be stopped immediately and medical treatment must be instituted with the usual appropriate emergency measures (e.g. administration of antihistamines, corticosteroids, sympathomimetics and, where necessary, ventilation).

Seizures:

Appropriate emergency medical measures should be taken, such as maintaining the airways open and administering antispasmodic drugs.

4.3 **General measures to be taken in the event of side effects**

If you notice any of the side effects mentioned above or any other unwanted effects not mentioned in this package leaflet during treatment with Tarivid 200 mg film-coated tablets, please inform your doctor or pharmacist.

If a side effect occurs suddenly or becomes intense, inform a doctor immediately as certain adverse drug reactions can be life-threatening in some circumstances (e.g. pseudomembranous colitis, some changes in the blood count, severe anaphylactic or anaphylactoid reactions and severe skin reactions). In these cases, do not continue taking Tarivid 200 mg film-coated tablets without consulting a doctor.

5. STORING TARIVID 200 MG FILM-COATED TABLETS

Keep out of the reach of children.

Do not use after the expiry date printed on the carton and container.

6. FURTHER INFORMATION

What Tarivid 200 mg film-coated tablets contain:

- The active substance is ofloxacin. 1 film-coated tablet contains 200 mg of ofloxacin.
- The other ingredients are lactose monohydrate, corn starch, carmellose sodium, hydroxypropyl cellulose, magnesium stearate (Ph. Eur.) [of vegetable origin], hypromellose macrogol 8000, talc and titanium dioxide (E 171).

Contents of the pack:

Tarivid 200 mg film-coated tablets is available in pack of 10 film-coated tablets.

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This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

PIL064/2