

A guide for patients to metoject®/metex®



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Dear patient,

Psoriasis is one of the most common skin diseases in our part of the world, affecting just over 2% of the population in western countries. It is not a cosmetic defect, but a severe, lifelong chronic disease. About a quarter of people who suffer from psoriasis experience not only skin problems but also joint symptoms ranging from mild swelling to severe pain with impairment of mobility. This is known as psoriatic arthritis.

A range of treatments are now available for psoriasis and psoriasis with involvement of the joints. The doctor will choose the right treatment depending on the patient and his/her needs.

Among other factors, efficacy, the severity of the illness and safety of treatment play an important part. Your doctor has decided with you on a treatment containing the active substance methotrexate. Methotrexate at a low dose (up to 30 mg/week) is the most commonly used medication worldwide for internal (systemic) treatment of psoriasis.

In the following pages, we will provide you with information about psoriasis and psoriatic arthritis, accompanied by practical tips for everyday life.

We wish you all the best for a successful therapy!

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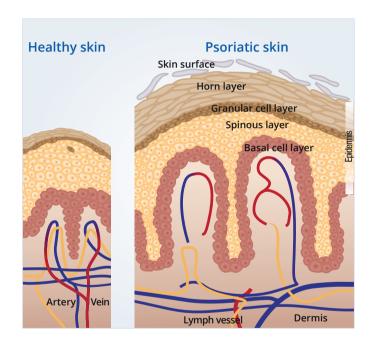
Explantion

What is psoriasis vulgaris?

Typical symptoms of the most common form of psoriasis, psoriasis vulgaris (occurring in about 80% of cases) are scaly skin and inflamed and reddened, often itchy patches of skin (plaques).

These plaques can occur on different parts of the body. They most commonly occur on the extensor side of elbows or knees, on the scalp and on the lower back.

Psoriasis vulgaris usually occurs spasmodically, i.e. there are times when symptoms become almost invisible or imperceptible and symptoms then recur after an interval of varying length. Triggers can include stress, bad diet, infections, body care products and medication.



Changes in the skin

The skin in the plaques is characterised by significant changes:

- Disturbances to growth
- Changes in blood vessels
- Inflammatory processes

In psoriasis vulgaris, most of the skin changes occur in the upper two layers of skin, the epidermis and the dermis (corium). In healthy skin, the cells that make up the horny layer of the epidermis (keratinocytes) take around 28 days from formation to when they are removed from the outer surface of the skin through scaling.

The epidermis of psoriasis plaques is about four times as thick as that of healthy skin. This is because cell division is increased up to 8-fold. This

disrupts the growth of the skin cells that make up the horny layer, so that the migration of skin cells takes just a few days, instead of 28 days as in healthy skin. This means that many cells are not yet mature when they reach the upper layer of skin, and large clusters of immature skin cells form. The thickened horny layer therefore comes loose, and scales become visible.

These inflammatory processes occur in the dermis, where blood vessels multiply. This leads to an increase in blood flow to the dermis. The coarse, scaly epidermis means that the dermis underneath is less well protected and it is easier for injury and bleeding to occur, which causes more and more cells from the body's own defence system (inflammatory cells) to accumulate in the skin.

As well as psoriasis vulgaris, which we have described above and which is the type that about 80% of people affected by psoriasis suffer from, there are also other forms of the disease

- Inverse psoriasis (affecting skin folds) deep red plaques, usually occurring in moist skin folds such as those in the abdomen, genital area and buttocks, as well as the armpits and bends of the knees and elbows, characterise the external appearance of this form of psoriasis, which tends to be rare. It occurs in around 5% of patients.
- Scalp psoriasis (psoriasis capitis) scalp psoriasis occurs on the scalp, but the lesions are not necessarily restricted to the areas that are covered by hair and may extend several centimetres into skin where there is no hair. About half of all people with psoriasis suffer from this type, and in some patients only the scalp is affected.

- **Guttate psoriasis** this occurs most commonly in children and adolescents. Instead of thick plaques, this form of psoriasis involves small, red, dot-like patches that look like drops of water distributed over the body. It is often caused by a streptococcal infection (e.g. tonsillitis) and in 30–70% of cases becomes chronic.
- **Pustular psoriasis** pustular psoriasis is a very rare, special form of psoriasis, in which blisters (pustules) filled with pus form on reddened skin. It may affect only the palms of the hands and soles of the feet; with the "generalised form", which is rarer, the whole body is affected.
- Nail psoriasis the fingernails and toenails are often affected by psoriasis. This is known as nail psoriasis. In about 50% of psoriasis patients, the nails are affected.

Around a quarter of psoriasis patients with skin symptoms also experience swollen and/or inflamed joints. This is psoriatic arthritis, which we will look at in the next few pages.

Symptoms and progression of the disease

The name ,psoriasis' reveals two key characteristics of the disease

- 1 The usually fine, yellowish to silvery-white scales arise because too many new cells are forming too quickly in the affected areas of skin. These scales consist of dead cell residues that are stuck to each other and to the cells underneath. Cells also die in the superficial layers of healthy skin, but their residues are much less likely to stick and instead flake off almost imperceptibly.
- 2 Below the scales is a pale to deep red patch, which may be raised to some extent. Red means inflammation. A wide red margin overlapping the scaly area indicates inflammation and shows that the psoriasis is getting worse. The affected skin is very itchy in many cases.

In the initial stages, the symptoms (signs) of ordinary psoriasis (psoriasis vulgaris) are not characteristic.

The characteristic scales are often absent. The right diagnosis can usually only be made if many similar small psoriasis lesions have formed within a few weeks (exanthematous psoriasis, from exanthema – rash) or if plaques have formed over several months to years, which may be larger than the palm of the hand and which change only slowly (chronic stationary psoriasis).

The two types of ordinary psoriasis that have been described are usually treated with ointments, baths, phototherapy and similar treatments. This is often not sufficient to combat severe psoriasis, however, an internal treatment (e.g. with tablets, injections or pre-filled autoinjectors) is required.

Severe psoriasis does not tend to subside spontaneously. It is characterised by more pronounced inflammation and may lead to pustules, cover the entire skin (erythroderma – red skin) or even affect the joints and the nails.

A distinction is made between two types of psoriasis depending on genetic predisposition. If psoriasis begins before the age of 40 (type I), progression is severe and the patient's parents are often also affected. In contrast, if psoriasis first occurs after the age of 40 (type II), it tends to be mild, chronic stationary psoriasis.

What is psoriatic arthritis (PsA)?

Arthritis means inflammation of the joints. As psoriasis progresses, it may begin to affect the joints. Both small and large joints can be affected.

Arthritis can be mild to severe. Psoriatic arthritis is often not recognised as such until years after the skin is first affected. Psoriatic arthritis can be distinguished from arthritis due to other causes

through careful examinations and special laboratory tests.

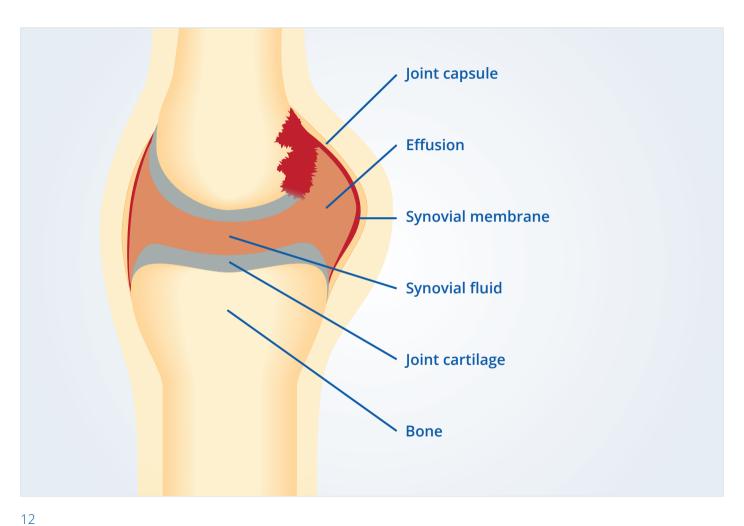
Psoriatic arthritis should be diagnosed as early as possible, so that it can be treated at an early stage. Internal treatment is generally required. If it is not adequately treated, the arthritis will progress continuously and lead to destruction of the joints.

Symptoms and progression of the disease

Psoriatic arthritis, also known as psoriatic arthropathy (from the Greek arthron ,joint' and -pathy ,disease'), is an inflammatory joint disease that occurs in some patients with psoriasis.

About 30% of all patients with psoriasis suffer from psoriatic arthritis.

The joint disease often occurs many years after the skin symptoms appear. However, about one in four patients with psoriatic arthritis experience joint problems at the same time or even before the skin symptoms. The inflammatory process in psoriatic arthritis tends to originate in the synovium (synovial membrane). This specialised mucous membrane secretes the fluid that lubricates the joint (synovial fluid), which ensures smooth movement and protects the bone against wear. In psoriatic arthritis, the synovial membrane becomes thickened due to the ongoing inflammatory process. This leads to swelling and pain in the joint. Production of synovial fluid also increases, leading to effusion (accumulation of fluid).



The tissue that is irritated in this way begins to proliferate uncontrollably and grows into the adjacent bone. As proliferation increases, the joint cartilage and bone start to be destroyed.

Psoriatic arthritis should therefore be diagnosed and treated as early as possible. If it is not adequately treated, joint destruction is certain to follow.

Psoriatic arthritis occurs in various forms

- Asymmetrical form (oligoarthritis) over 50% of cases of psoriatic arthritis involve the asymmetrical form. Progress tends to be mild, with only a few inflamed joints. However, these joints are usually swollen and sore.
- Symmetrical polyarthritis this is the second most common form of psoriatic arthritis, accounting for 30% to 40% of cases. In symmetrical polyarthritis, inflamed joints are usually distributed symmetrically. Unfortunately, progression of this form is often severe.

- Mutilating arthritis a form of psoriatic arthritis that is usually associated with relatively severe progression. It often affects many joints in the hands and feet as well as the intervertebral joints and/or sacroiliac joints. It occurs in around 5% of all cases of psoriatic arthritis.
- Spondyloarthritis (inflammation of the vertebrae) this form of psoriatic arthritis occurs in up to 15% of patients, usually together with other forms. It affects the sacroiliac joints and/ or the intervertebral joints. There is often impaired movement and pain in the spine. However, the patient may not experience any significant symptoms.

Treatment

Treatment for psoriasis and psoriatic arthritis

Psoriasis and psoriatic arthritis are chronic diseases that cannot be prevented. However, there is a wide range of effective treatment methods, which allow symptoms and pain to be reduced considerably.

Various factors come into play when choosing the right treatment for the patient. The doctor will consider carefully which treatment is right for the patient, taking into account the following points:

- The severity of the disease
- The extent to which the psoriasis/psoriatic arthritis is causing the patient to suffer
- How practical the treatment is to use (e.g. frequency of use, time required to administer)
- Interactions with other medicines

- Patient's wish for a safe medicine that is used frequently
- Need for long-term medication

Overview of treatment for psoriasis vulgaris

Topical (local) treatments: external treatment with an ointment, gel, cream or lotion, e.g. glucocorticoids (synthetically produced active substances that are similar to cortisone), salicylic acid, urea, vitamin D3 analogues and coal tar.

Phototherapy/light therapy: radiation therapy for the affected skin over several weeks with increasing doses of UV light, e.g. UVB, PUVA treatment (radiation therapy with ultraviolet light (UVA) combined with light-sensitising medication) and balneophototherapy (bathing in brine or salt water followed by UV radiation). Due to the risk of skin cancer and premature ageing of the skin, this treatment can be used for only a limited period.

Conventional systemic treatments: for internal treatment in the form of tablets, injections, pre-filled pens or infusions, e.g. ciclosporin, retinoids or methotrexate. Please see page 18 for further details on methotrexate.

Treatment with biologic agents (systemic): internal treatment that works by influencing the immune system. These medicinal products are produced biotechnologically in genetically modified organisms and block pro-inflammatory substances. They are usually administered in the form of injections, prefilled pens or infusions. Biologic agents are usually used only when conventional systemic treatments do not have an adequate effect.

Overview of treatment for psoriatic arthritis

Cortisone-free anti-inflammatory drugs: these non-steroidal anti-inflammatory drugs (NSAIDs) or antiphlogistics are described as classic rheumatism drugs. They have an anti-inflammatory and pain-relieving effect, but some of these substances can make skin problems worse or can cause severe gastrointestinal symptoms.

Glucocorticoids (cortisone): these are active substances that are similar to cortisone, with strong anti-inflammatory properties, and are also referred to in medical terminology as corticoids or steroids. If only one or a few joints are affected, these are injected directly into the joint in the form of a suspension for acute episodes of the disease. Long-term use may lead to side effects such as thinning of the skin, osteoporosis and development of oedema. The aim is therefore generally to limit the period of treatment.

Conventional systemic treatments: internal treatment in the form of tablets, injections, pre-filled pens or infusions, e.g. leflunomide or methotrexate.

- ▶ Leflunomide inhibits the production of cells that are involved in immune defence and that cause inflammation. (Taken once daily as a tablet).
- ▶ Methotrexate inhibits inflammation and regulates the function of the immune system. It is effective in combating skin changes and joint inflammation and is authorised for both indications. (Taken once a week).

Treatment with biologics and JAK inhibitors (systemic)

Internal treatments that work by influencing the immune system. Biologics are produced biotechnologically in genetically modified organisms and block pro-inflammatory substances. They are usually administered with pre-filled pens, syringes or infusions. JAK inhibitors, taken as tablets, modulate the immune system. Biologic agents are used only when conventional systemic treatments do not have an adequate effect..



The active substance methotrexate

Methotrexate (MTX) is the medicine most commonly used worldwide as internal treatment for psoriasis and has been in use for over 40 years. Its pharmaceutical forms have been improved in recent years, which has also led to improvements in its properties, including the desired effects and side effects.

Dermatologists and patients have gained a great deal of experience in the use of methotrexate, having used it for many years.

Dosage and pharmaceutical forms

Patients with psoriasis or psoriatic arthritis are given a very small dose of methotrexate once a week, usually in the evening. The normal dose is between 7.5 and 25 mg per week.

MTX usually starts to take effect gradually after 4–8 weeks. If it has not proved sufficiently effective after 8 weeks, an increase in the dose is recommended

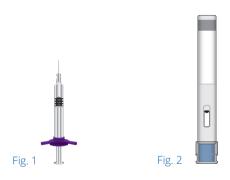
Methotrexate can be taken in the form of tablets (orally) or can be injected into the muscles (intramuscularly), into a vein (intravenously) or under the skin (subcutaneously).

metoject®/metex® pre-filled syringes and pre-filled autoinjector PEN are available for subcutaneous administration of methotrexate. The patient can administer these him/herself at home without any problems, after a detailed explanation has been provided by the doctor.

Methotrexate tablets show fluctuations in individual bioavailability, unlike pre-filled syringes and pre-filled pens of methotrexate. That means that the quantity of the active substance that is absorbed may be different each time a tablet is taken. In contrast, almost the entire quantity of active substance given has an effect following subcutaneous administration.

metoject®/metex® syringes and PEN (see Fig. 1 and 2) are available in a wide range of doses. The doctor choses the right dose for you.

metoject®/metex® PEN has a two-step injection process. First, you remove the cap. Then, you position the pen and hold it straight on the injection side for injecting your medicine.



Methotrexate for treatment of psoriasis or psoriatic arthritis is administered only once a week on the same weekday.

Follow-up examinations

Nowadays, we talk about the informed patient, who works with the doctor on an equal footing. Complicated diseases and effective medicines require the doctor and the patient to have specialist knowledge. This primarily concerns control of the desired effects and of unwanted side effects. Both can be reliably assessed with a few questions and examinations. A special monitoring programme has been developed for methotrexate treatment. This includes regular laboratory tests, which only require very small quantities of blood. Particular attention is paid to potential liver damage and infections.

The doctor providing treatment decides how often laboratory tests will be carried out. This depends on changes in laboratory values during treatment. A blood sample is usually taken once a week initially. If the values remain normal/stable, checks will be carried out at longer intervals.

Side effects

Side effects are still possible even at this low dose, as with any medication. It is a well-known principle that a medicine that has an effect can also have side effects applies. For example, patients may experience side effects such as nausea, fatigue or changes in the liver.

Should side effects occur, the patient must contact his/her doctor. There are certain strategies for alleviating these side effects, e.g. taking folic acid.

Administration of folic acid

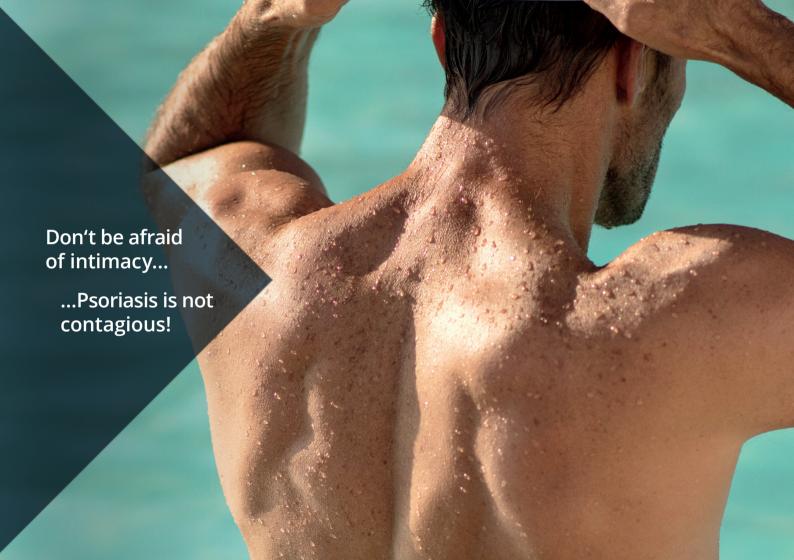
Folic acid (vitamin B9) is a vitamin that plays an important part in cell division and that the human body cannot produce itself (see fig. 3). Folic acid metabolism is often deficient in patients with psoriasis. Tolerance of MTX can be improved by administering small quantities of folic acid. Your doctor will give you the relevant information about dosage and administration of folic acid.

Contraception during MTX treatment

- Both women and men must use a reliable method of contraception during treatment with methotrexate.
- Please tell your doctor immediately if you become pregnant during treatment with methotrexate.

Patients must not become pregnant or father a child during treatment with methotrexate. There is a risk that the child could be born with defects.

Consistent use of contraception is therefore necessary in men and women. If you are planning a pregnancy, women must discontinue MTX at least 6 months beforehand, men 3 months beforehand.



Coping with Psoriasis every day

The psychological effects of psoriasis

Making contact with other sufferers

Every patient finds it hard initially to get used to the disease and accept it as a new part of their life. It is often helpful to discuss your experiences with other patients in self-help groups or internet forums. Not only will this make you more confident, it will also help you to deal more easily with people who are not affected. Above all, it is important to make it clear to other people that the disease is not contagious or due to lack of hygiene. By providing them with the facts, you can quickly allay any fears about physical contact and any preconceptions about the disease.

Find new confidence!

Many patients have a tendency to withdraw and to neglect or restrict social contact during phases of increased disease activity, as they are not sure whether other people will accept them because of their appearance.

This can lead to social isolation and even depression. It is therefore particularly important for the doctor to take time to talk to the patient about any fears or concerns and to provide the patient with the information he/she needs.

Concomitant psychotherapy, either on an individual basis or in a group, can often be an effective way to give affected patients back some courage and strength. It is important to understand your illness in order to be able to cope with it in daily life.

Relaxation techniques

Stress and psychological burdens can increase the likelihood of episodes of the disease occurring or can exacerbate existing symptoms.

Learning appropriate relaxation techniques can help to provide relief and enable patients to calm down again. Autogenic training and yoga are among the most commonly used methods.

Three relaxation exercises

- 1 Place your hands loosely on your abdomen (at about the level of your navel). Now try to breathe in slowly and notice how your abdominal wall slowly rises and falls. You should inhale and exhale gently and evenly, counting to three while you do so.
- 2 Pull your shoulders up as far as you can and then relax them again.
- 3 Lean your head back as far as you can while in an upright position, then bring it forward again. This will relax your neck muscles.

Clothing

Prevent new areas of skin from becoming affected by wearing the right clothing:

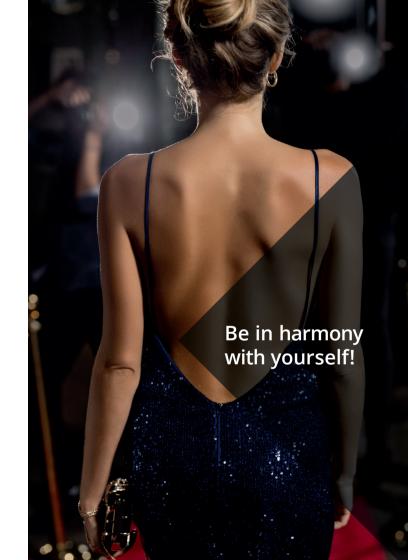
Patients suffering from psoriasis should first of all ensure that their clothing is loose and allows as much air as possible to get to the skin. Their skin will react just as sensitively to pressure and friction as to heat and increased sweating.

Clothing that is too tight and abrasive is high up on the list of known initial triggers. If some areas of the body are already affected, mechanical irritation at other points on the body can cause symptoms.

The following factors may be involved in outbreaks of psoriasis on areas of intact skin:

- Footwear that is too tight or boot legs that are abrasive
- Rough or coarse fabrics (including sheep's wool)
- Constrictive belts
- Abrasive seams
- Scratches on the skin
- Jewellery and watches

Try to wear clothing that is as soft and loose as possible and made from breathable fabrics, and wear comfortable footwear. Your skin will thank you for it!





Recipes

Delicious recipes that can help with your wellbeing

The following recipes are intended to give you an insight into the variety of cuisine that psoriasis sufferers can enjoy. It is particularly important if you have psoriasis to look at different foods and their ingredients. In this way, you can research for yourself what is good for your body and what it will react to. A balanced, conscious diet will do you and your skin a lot of good.

Delicious vegetables

Skewers of colourful vegetables with tomato sauce

Serves 2

Ingredients

Vegetable skewers

400 g vegetables (e.g. courgettes, peppers, aubergines, spring onions, mushrooms, sweetcorn), soy sauce & iodised salt

Tomato sauce

300 g tomatoes, 1 onion, 10 g margarine (free from milk protein), 1/2 tablespoon tomato purée, 1 garlic clove (crushed), lodised salt

Preparation

First wash the vegetables and chop them into pieces of equal size.

Slide the vegetable pieces onto wooden skewers. Brush with soy sauce and sprinkle with iodised salt. The skewers can be fried in a pan or barbecued.

To make the sauce, skin the tomatoes (cut into them crosswise and scald them with hot water)

and then dice them.

Dice the onions and lightly braise everything in a pan with margarine. Add the tomato purée and bring to the boil.

Season with garlic and salt.



Potatoes with vegetables

Serves 8 Ingredients

8 large potatoes, 400 g mushrooms, 2 leeks, 2 apples, margarine (free from milk protein), iodised salt

Preparation

Wash the potatoes very carefully and boil them in water. Do not allow the potatoes to become too soft, as they will need to be scooped out.

Wash and slice the mushrooms and leeks. Core the apples and grate them coarsely. Lightly braise everything in a pan with the margarine.

Scoop out the potatoes using a melon baller or spoon and add the potato mixture to the vegetables. Season with iodised salt.

Then place the potato skins in a baking dish and fill them with the potato and vegetable mixture. Place a small knob of margarine on each potato and bake in the oven for approximately 15 minutes at 200°C.



Hearty fare

Tuna carpaccio

Serves 8 Ingredients

200 g radishes, 2 limes, 2 pieces of fresh ginger (approx. 1 cm), 400 g fresh tuna, 4 tablespoons soybean oil, iodised salt, 1 pinch coriander

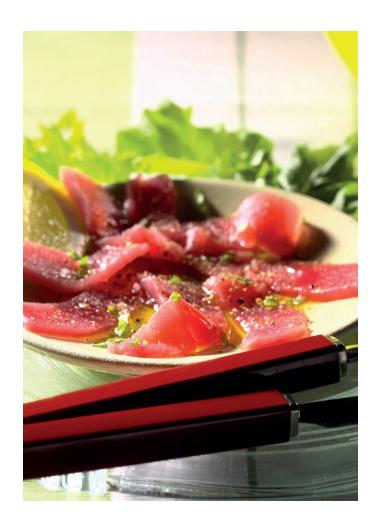
Preparation

Peel the radishes and chop into fine slices, then into strips.

Remove the rind from the limes and chop the flesh into small cubes. Make sure you remove the pips. Peel and finely grate the ginger.

Cut the tuna into thin slices with a very sharp knife and lay the slices on a plate.

Mix the radishes, lime cubes and ginger with the oil and season with iodised salt and coriander. Spread over the tuna and serve immediately.



Juicy burgers

Serves 6 Ingredients

Burgers

1/2 onion, 300 g minced beef, 3 tablespoons mineral water, 2-3 tablespoons rolled oats; iodised salt, 1-2 tablespoons soy meal, rapeseed oil; 1/3 of a red, green and yellow pepper, 1/3 cucumber, 2 tomatoes; lettuce leaves, burger baps

Preparation

Finely dice the onions. Halve the peppers, wash and finely dice.

Mix the minced beef with the onion and pepper cubes, mineral water and oats and a little iodised salt. Add enough soy meal to ensure a firmer consistency.

Make 6 flat burgers from this mixture and fry in oil on both sides in a pan.

Peel the cucumber. Wash and slice the tomatoes. Rinse the lettuce leaves.

Cut open the bread rolls and cover them with lettuce. Then place the burgers inside, along with the cucumber and tomato slices, and close the bread rolls again.



Sweet dessert

Sweet banana fritters

Serves 8 Ingredients

200 g oatmeal (fine), 200 g spelt flour (fine), apple juice, 80 g melted margarine (free from milk protein), 1 pinch iodised salt, 4 mashed bananas, 100 g ground almonds, a little water if needed, rapeseed oil for baking, puréed apple

Preparation

Thoroughly mix together the oatmeal and spelt flour with the apple juice, iodised salt and mashed bananas.

Cover this dough and leave it to rise for about 20 minutes.

Add the almonds and a little water to the dough and mix well.

Then heat the oil in a pan and spoon in the dough in portions.

Cook the fritters on both sides on a medium heat. Serve on a plate with puréed apple.



Raspberry dream

Serves 5 Ingredients

75 g raspberries, 75 ml honey, 375 ml sour cherry juice, 0.5 l carbonated mineral water

Preparation

Carefully wash the raspberries and put them in a container (punchbowl or carafe).

Pour the honey over them, cover and leave for at least 1 hour to allow it to infuse.

Then pour the sour cherry juice over the top and refrigerate. Top up with mineral water before serving and garnish with a slice of orange.



What kind of exercise is good for me?

Exercising as a group or with friends is more fun and will motivate you to exercise regularly.

Exercise can help to reduce stress. Your awareness and acceptance of your body improves, which will also strengthen your self-esteem.

Please make sure you wear comfortable clothing

that will allow the air to get to your skin. If you are unsure what clothes you can wear, contact your dermatologist or ask for advice in a sports shop.

Don't forget to take appropriate skin care measures, particularly after exercising.

POSSIBLE TYPES OF EXERCISE				
For Psoriatic-Arthritis	For Psoriasis			
• Cycling	• Yoga			
· Aqua jogging	• Tennis			
· Aqua aerobics	• Football			
• Hiking	 Running/Nordic walking 			
Nordic walking				
 Aerobics 				



Info

Frequently asked questions

Is psoriasis contagious?

No! Psoriasis is not contagious or transmittable in any way.

Does psoriasis affect my life expectancy?

There is to date no known impairment in terms of the mild forms of psoriasis. However, severe psoriasis can lead to certain secondary or concomitant diseases. Treatment and regular check-ups are therefore important.

Does psoriasis damage your hair?

Not in most cases. However, if you have a thick layer of scales on your scalp, your hair may become brittle or may start to thin. In some cases you may also lose some hair. However, if the psoriasis on your head gets better the hair usually grows back.

Does the weather affect psoriasis?

Many psoriasis sufferers have more problems with their skin in the winter than in the summer. That could be due to a lack of sunlight. However, it is not possible to generalise.

How do I shave and remove body hair when I have psoriasis?

Psoriasis shouldn't stop you from shaving. It is important for each patient to choose the best method for his/her skin type and for the area of the body concerned. Arms and legs, for example, can be shaved with a manual or electric razor. It is important not to pull the hairs out. Permanent hair removal may be the best option for sensitive skin folds. Men should take particular care when shaving their faces not to irritate scaly areas and to avoid cuts.

What can trigger an episode of psoriasis?

- Acute infections: flu or a cold
- Chronic inflammation in the body
- Stress
- Climatic factors (e.g. air from heating systems in the winter)
- Hormonal fluctuations (e.g. during pregnancy)
- Being overweight
- Alcohol
- Medication

Notes			

Further Questions?

Do not hesitate to contact medac GmbH or your healthcare professional

You can also get more information on our website www.metoject.com



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