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 have any further questions, ask 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 Decortin H is and what it is used for
2. Before you take Decortin H
3. How to take Decortin H
4. Possible side effects
5. How to store Decortin H
6. Contents of the pack and other information

1. WHAT DECORTIN H IS AND WHAT IT IS USED FOR

Decortin H is a glucocorticoid (corticosteroid) with an effect on the metabolism, salt (electrolyte) balance and on tissue functions.

Decortin H is used in diseases requiring systemic glucocorticoid treatment. These include, depending on the nature of symptoms and severity (see section 3.2. Dosage for dosing table with dosages DS: a to d and dosage e.):

Hormone replacement therapy for
- reduced or absent adrenal cortex function (adrenocortical insufficiency) regardless of the cause (e.g. Addison’s disease, adrenogenital syndrome, surgical removal of the adrenal glands, underactive pituitary gland) beyond growing age (first-choice agents are hydrocortisone and cortisone).
- stress conditions after long-term corticosteroid therapy

Rheumatic diseases:
- active phases of vascular disease:
  - panarteritis nodosa (nodular inflammation of the blood vessel walls) (DS: a, b; duration of treatment restricted to two weeks in cases of existing hepatitis B infection)
  - giant cell arteritis, muscle pain and stiffness (polymyalgia rheumatica) (DS: c)
  - temporal arteritis (inflammation mainly affecting the temporal artery (DS: a), in cases of acute visual loss, initially high-dose pulse therapy with intravenous glucocorticoids (through a vein) and long-term therapy with ESR (erythrocyte sedimentation rate) monitoring
  - Wegener’s granulomatosis: induction therapy (DS: a-b) in combination with methotrexate (milder forms not affecting the kidneys) or according to Fauci’s regimen (severe forms
affecting the kidneys and/or lungs), remission maintenance: (DS: d, tapered treatment) in combination with immunosuppressants

- Churg-Strauss syndrome: initial therapy (DS: a-b), with organ manifestations and severe forms in combination with immunosuppressants, remission maintenance (DS: d)

- active phases of rheumatic disease that can affect internal organs (DS: a, b): lupus erythematosus affecting the internal organs, muscle weakness and pain (polymyositis), inflammation of the cartilage (chronic atrophic polychondritis), mixed connective tissue disease

- active rheumatoid arthritis (DS: a to d) with severe, progressive forms, e.g. rapidly destructive, progressive forms (DS: a) or forms not affecting the joint (DS: b)

- other forms of inflammatory rheumatic joint disease, provided that the severity of symptoms requires it and certain antirheumatic medicines (NSAIDs) are not effective or cannot be used

- inflammatory changes mainly affecting the spine (spondylarthritis) spinal inflammation and changes (ankylosing spondylitis) affecting other joints, e.g. arms and legs (DS: b, c), psoriatic arthritis (affecting the joints) (DS: c, d), joint disease caused by gastrointestinal disorders (enteropathic arthritis) with high inflammatory activity (DS: a)

- arthritis as a reaction to other underlying diseases (DS: c)

- arthritis in cases of sarcoidosis (DS: b initially)

- heart inflammation in rheumatic fever, over 2-3 months in severe cases (DS: a)

- severe progressive forms of adolescent arthritis with no known cause (juvenile idiopathic arthritis), affecting the internal organs (Still’s disease) or forms affecting the eye (inflammation of the iris and surrounding area) which do not respond to topical treatment (DS: a)

**Bronchial and lung diseases:**

- bronchial asthma (DS: c-a), co-administration of medicines to widen the bronchial tubes is recommended

- acute worsening of COPD (chronic obstructive pulmonary disease) (DS: b); recommended duration of treatment up to 10 days

- specific lung diseases, such as acute alveolitis (inflammation of the air sacs) (DS: b), pulmonary fibrosis (hardening of lung tissue and changes in lung structures) (DS: b), bronchiolitis obliterans with organising pneumonia (BOOP) (DS: b tapered treatment), if necessary in combination with immunosuppressants, chronic eosinophilic pneumonia (DS: b tapered treatment), for the long-term treatment of chronic forms of stage II and III sarcoidosis (with shortness of breath, cough and deterioration in lung function tests) (DS: b)

- preventive treatment of respiratory distress syndrome in premature babies (DS: b, two individual doses)

**Upper respiratory tract diseases:**

- severe forms of hay fever and allergic rhinitis, after failure of nasal sprays containing glucocorticoids (DS: c)

- acute constriction of the larynx and airways: swelling of the mucous membranes (angioedema), obstructive pharyngitis (pseudocroup) (DS: b a)

**Skin diseases:**

Diseases of the skin and mucous membranes, which, due to their severity and/or extent - or because they affect the internal organs - cannot be adequately treated with topical glucocorticoids. These include:

- allergic or allergic-like reactions, allergic reactions associated with infections: e.g. hives (acute urticaria), shock-like (anaphylactoid) reactions

- serious skin diseases, some of which destroy the skin, drug-related rash, erythema exsudativum multiforme, toxic epidermal necrolysis (Lyell’s syndrome), acute generalised pustulosis, erythema nodosum, acute febrile neutrophilic dermatosis (Sweet’s syndrome), allergic contact eczema (DS: b to a)

- skin rash: e.g. allergic skin rash, such as atopic eczema or contact eczema, rash caused by pathogenic germs (nummular eczema) (DS: b to a)

- diseases with nodular formation: e.g. sarcoidosis, lip inflammation (cheilitis granulomatosa) (DS: b to a).
- severe skin diseases with blistering: e.g. pemphigus vulgaris, bullous pemphigoid, benign mucous membrane pemphigoid, linear IgA dermatosis (DS: b to a)
- inflammation of the blood vessels: e.g. allergic vasculitis, polyarteritis nodosa (DS: b to a)
- diseases of the body’s immune system (autoimmune diseases): e.g. dermatomyositis, systemic scleroderma (indurative phase), chronic discoid and subacute cutaneous lupus erythematosus (DS: b to a)
- severe skin diseases during pregnancy (see also “Pregnancy” and “Breast-feeding”): e.g. herpes gestationis, impetigo herpetiformis (DS: d to a)
- severe skin diseases with inflamed redness and scaling, e.g. pustular psoriasis, pityriasis rubra pilaris, parapsoriasis group (DS: c to a); erythroderma, including cases of Sezary’s syndrome (DS: c to a)
- other severe diseases: e.g. Jarisch-Herxheimer reaction in penicillin treatment of syphilis, cavernous haemangioma with rapidly progressive proptosis, Behcet’s disease, pyoderma gangrenosum, eosinophilic fasciitis, lichen ruber exanthematicus, hereditary epidermolysis bullosa (DS: c to a)

**Blood diseases/tumour diseases:**
- autoimmune disorders of the blood: anaemia due to self-destruction of red blood cells (autoimmune haemolytic anaemia) (DS: c to a), idiopathic thrombocytopenic purpura (Werlhof’s syndrome) (DS: a), acute decrease in the number of blood platelets, occurring in phases (intermittent thrombocytopenia) (DS: a)
- malignant diseases, such as: acute lymphoblastic leukaemia (DS: e), Hodgkin’s disease (DS: e), non-Hodgkin’s lymphoma (DS: e), chronic lymphatic leukaemia (DS: e), Waldenström’s disease (DS: e), multiple myeloma (DS: e)
- increased blood calcium levels associated with underlying malignant disease (DS: c to a)
- prevention and treatment of vomiting induced by chemotherapy (DS: b to a)
- palliative therapy of malignant diseases
Note: Decortin H can be used to relieve symptoms, e.g. in cases of reduced appetite, anorexia and general weakness in advanced cases of malignant disease, after other treatment options have been exhausted.

**Nervous system disorders:**
- certain forms of muscle paralysis (myasthenia gravis) (first-choice agent is azathioprine), chronic Guillain-Barré syndrome, Tolosa-Hunt syndrome, polyneuropathy in monoclonal gammopathy, multiple sclerosis (for tapering off treatment after high-dose infusion of glucocorticoids for an acute episode), certain forms of infant epileptic disorders (jack-knife seizures).

**Certain forms of infectious diseases:**
- toxic states in severe infectious diseases (in combination with antibiotics/chemotherapy agents), e.g. tuberculous meningitis (DS: b), severe forms of pulmonary tuberculosis (DS: b)

**Eye disorders (DS: b to a):**
- in disorders affecting the eye and in immunological processes in the eye socket and eye: optic nerve disease (optic neuropathy, e.g. in giant cell arteritis, caused by blood circulation problems or injury), Behcet’s disease, sarcoidosis, endocrine orbitopathy, orbital pseudotumor (swelling of tissue in the eye socket), transplant rejection and in certain forms of uveitis (inflammation of the uvea or middle layer of the eye), such as Harada’s disease and sympathetic ophthalmia

In the following disorders, administration of Decortin H is indicated only after unsuccessful topical treatment. Inflammation of various sections of the eye:
- inflammation of the sclera (outer layer) and surrounding area, cornea or uvea (middle layer), chronic inflammation of the section that produces aqueous humour (liquid in the eye), allergic conjunctivitis, alkali burns
- inflammation of the cornea, occurring in autoimmune disease or syphilis (additional treatment against pathogens required), for corneal inflammation caused by Herpes simplex (only if the
corneal surface is intact and accompanied by regular monitoring by an eye specialist).

**Gastrointestinal disorders/liver disorders:**
- ulcerative colitis (DS: b to c)
- Crohn’s disease (DS: b)
- autoimmune liver disease (autoimmune hepatitis) (DS: b)
- caustic oesophageal burns (DS: a)

**Kidney disorders:**
- certain autoimmune disorders in the kidney region: minimal change glomerulonephritis (DS: a), extracapillary proliferative glomerulonephritis (rapid progressive glomerulonephritis) (DS: high-dose pulse therapy, generally in combination with cytostatics), tapering off and ending treatment for Goodpasture’s syndrome; for all other forms, long-term continuation of treatment (DS: d)

2. **BEFORE YOU TAKE DECORTIN H**

**Do not take Decortin H**
if you are allergic (hypersensitive) to prednisolone or any of the other ingredients of Decortin H.

Apart from allergic reactions, there are otherwise no contraindications for the short-term use of Decortin H in acutely life-threatening pathological situations.

**Take special care with Decortin H**
if Decortin H has to be used at doses higher than those used in hormone replacement therapy: In this case, Decortin H should be taken only if your doctor regards it absolutely necessary in the following disorders.

Due to suppression of the body’s immune system, treatment with Decortin H can lead to an increased risk of bacterial, viral, parasitic, opportunistic and fungal infections. The signs and symptoms of an existing or developing infection may be masked and hence difficult to recognise. Latent infections may become reactivated.

If any of the following diseases is present, medicines that target the pathogens (i.e. germs that cause disease) may also have to be taken at the same time.
- acute viral infections (hepatitis B, chickenpox, shingles, herpes simplex infections, corneal inflammation caused by herpes viruses)
- acute and chronic bacterial infections
- fungal disease with infestation of internal organs
- certain diseases caused by parasites (amoeba or worm infections). In patients with suspected or confirmed infection with dwarf threadworms (*Strongyloides*), Decortin H can lead to activation and mass proliferation of these parasites.
- lymph node disease after tuberculosis vaccination (if you have a history of tuberculosis, do not use this medicine unless you are taking anti-tuberculosis medication).
- infectious inflammation of the liver (HBsAg-positive chronic active hepatitis)
- poliomyelitis (polio)
- approximately 8 weeks before and up to 2 weeks after preventive vaccinations with an attenuated (weakened) pathogen (live vaccine).

During treatment with Decortin H, the following disorders must be closely monitored and treated according to need:
- gastrointestinal ulcers
- difficult-to-manage high blood pressure
- difficult-to-manage diabetes mellitus
- osteoporosis (“brittle bones”)
- mental (psychiatric) illnesses (and past history thereof), including suicidal risk. In this case, neurological or psychiatric monitoring is recommended.
- increased pressure inside the eye (narrow and wide-angle glaucoma); monitoring by an eye specialist and complementary therapy are recommended.
- corneal lesions and ulceration in the eye; monitoring by an eye specialist and complementary therapy are recommended.

Due to the risk of bowel wall perforation, Decortin H may only be used in the following cases if there are compelling medical reasons and appropriate monitoring:
- severe inflammation of the large intestine (ulcerative colitis) with an imminent risk of perforation, with abscesses or purulent (pus-filled) inflammation, possibly even without peritoneal irritation
- diverticulitis (inflammation of bulging sacs [known as diverticula] on the bowel wall)
- immediately after certain types of bowel surgery (intestinal anastomosis)

Signs of peritoneal irritation after perforation of a gastrointestinal ulcer may be absent in patients receiving high doses of glucocorticoids.

The risk of tendon disorders, tendon inflammation and tendon rupture is increased when fluoroquinolones (certain antibiotics) and Decortin H are administered together.

When treating a certain form of muscle paralysis (myasthenia gravis), symptoms may get worse at the start of treatment. For this reason, adjustment of initial Decortin H treatment should take place in a hospital. Treatment with Decortin H should be introduced gradually, especially if the symptoms in the face and throat region are particularly severe or if breathing is impaired.

In principle, it is possible to give vaccinations with vaccines made from pathogens that have been “killed off” (inactivated vaccines). However, it should be remembered that successful vaccination may be compromised at higher doses of Decortin H.

During long-term treatment with Decortin H, regular medical check-ups (including eye examinations at three-monthly intervals) are required.

In cases of diabetes, metabolism must be regularly checked; a possibly increased need for medicines to treat diabetes (insulin, oral antidiabetics) must be considered.

Particularly during prolonged treatment at relatively high doses of Decortin H, adequate potassium intake (e.g. vegetables, bananas) must be ensured and salt intake restricted. Have your blood potassium levels monitored by your doctor.

Severe anaphylactic reactions (overreaction of the immune system) may occur.

If you have severe high blood pressure or severe heart failure, you should let your doctor carefully monitor you, as there is a risk of deterioration.

If episodes of particular physical stress occur during treatment with Decortin H, such as feverish illness, accidents or surgery, childbirth, etc., your doctor must be notified immediately or the emergency doctor must be informed about your current treatment. It may become necessary to temporarily increase the daily dose of Decortin H. During long-term treatment, your doctor should therefore provide you with a corticosteroid safety card, which you should carry with you at all times.

Depending on the dosage and duration of treatment, a negative effect on calcium metabolism must be taken into account and preventive treatment of osteoporosis is therefore recommended. This applies particularly if there are already existing risk factors, such as family predisposition, advanced age, insufficient protein and calcium intake, heavy smoking, excessive alcohol consumption, after the menopause and lack of physical exercise. Prevention consists of adequate
calcium and vitamin D intake, as well as physical exercise. In cases of existing osteoporosis, additional drug-based therapy should be considered.

The following risks should be considered when finishing - or interrupting - long-term treatment: fresh outbreak or worsening of the initial disease; acute adrenocortical insufficiency (underactive adrenal cortex function – particularly in stressful situations, e.g. during an infection, after accidents, in cases of increased physical stress); pathological signs and symptoms associated with cortisone withdrawal.

Viral diseases (e.g. measles, chickenpox) may become particularly severe in patients treated with Decortin H. At particular risk are patients with a weakened immune system (immunosuppressed patients) who have never had measles or chickenpox. If these persons should come into contact with people with measles or chickenpox during treatment with Decortin H, they should consult their doctor immediately, who will start preventive treatment as appropriate.

**Children and adolescents**
In children, due to the risk of growth inhibition, Decortin H should not be used unless there are compelling medical reasons and height gain must be regularly checked. Therapy with Decortin H should have a time limit or be administered on an alternating basis (e.g. at double the daily dose every other day (alternate-day therapy)).

**Elderly patients**
As elderly patients are at increased risk of osteoporosis, the benefit/risk ratio for treatment with Decortin H should be carefully considered.

**Important information about some of the ingredients of Decortin H**
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Effects if misused for doping purposes**
The use of Decortin H may lead to false-positive results in doping controls and use as a doping agent may endanger the health.

**Other medicines and Decortin H**
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

**Which other medicines influence the effect of Decortin H?**
- Medicines that speed up metabolism in the liver, such as certain sleeping medications (barbiturates), antiepileptic agents (phenytoin, carbamazepine, primidone) and certain medicines for tuberculosis (rifampicin) can weaken the effect of Decortin H.
- Ephedrine (may be contained, for example, in medicines for low blood pressure, chronic bronchitis, asthma attacks, nasal decongestants for blocked nose and as an ingredient in appetite stimulants): The effectiveness of Decortin H may be reduced due to accelerated metabolism in the body.
- Medicines that slow down metabolism in the liver, such as certain medicines for fungal disease (ketoconazole, itraconazole), can enhance the effect of Decortin H.
- Certain female sex hormones, e.g. used for contraception (the “Pill”): The effect of Decortin H may be enhanced.
- Medicines to treat excess acid production in the stomach (antacids): Reduced absorption of prednisolone is possible if magnesium hydroxide or aluminium hydroxide is given at the same time. The two medicines should therefore be taken at staggered intervals (2 hours).

**How does Decortin H influence the effect of other medicines?**
- Decortin H can enhance the effect of medicines used to strengthen the heart (cardiac glycosides) due to potassium deficiency.
Decortin H can increase the excretion of potassium by water tablets (saluretics) and laxatives.

Decortin H can reduce the blood sugar-lowering effect of oral antidiabetics and insulin.

Decortin H can weaken or enhance the effect of medicines used to prevent blood clotting (oral anticoagulants, coumarin derivatives). Your doctor will decide whether a dose adjustment of the anti-blood-clotting agent is required.

If used at the same time as medicines for inflammation and rheumatism (salicylates, indomethacin and other non-steroidal anti-inflammatory drugs), Decortin H can increase the risk of stomach ulcers and gastrointestinal bleeding.

Decortin H can reduce the blood sugar-lowering effect of oral antidiabetics and insulin.

Decortin H can weaken or enhance the effect of medicines used to prevent blood clotting (oral anticoagulants, coumarin derivatives).

Your doctor will decide whether a dose adjustment of the anti-blood-clotting agent is required.

If used at the same time as medicines for inflammation and rheumatism (salicylates, indomethacin and other non-steroidal anti-inflammatory drugs), Decortin H can increase the risk of stomach ulcers and gastrointestinal bleeding.

Decortin H can prolong the muscle-relaxing effect of certain medicines (non-depolarising muscle relaxants).

Decortin H can enhance the effect of certain medicines used to increase pressure within the eye (atropine and other anticholinergics).

Decortin H can reduce the effect of medicines for worm disorders (praziquantel).

If used at the same time as medicines for malaria or rheumatic disorders (chloroquine, hydroxychloroquine, mefloquine), Decortin H can increase the risk of muscle disease or heart muscle disease (myopathies, cardiomyopathies).

Growth hormones (somatropin): Their effect is reduced particularly at high dosages of Decortin H.

Decortin H can decrease the rise in thyroid-stimulating hormone (TSH) after administration of protirelin (a hormone of the hypothalamus in the brain).

Decortin H and combined use of medicines used to suppress the body’s immune system (immunosuppressants) can increase susceptibility to infections and aggravate already existing infections that may not yet have emerged.

Also for ciclosporin (a medicine used to suppress the body’s own immune system): Decortin H can increase ciclosporin levels in the blood and thereby increase the risk of seizures.

Certain medicines used to lower blood pressure (ACE inhibitors): Increased risk that blood count changes may occur.

Fluoroquinolones, a certain group of antibiotics, can increase the risk of tendon ruptures.

**Effect on testing methods:**
Skin reactions to allergy tests may be suppressed.

**Pregnancy and breast-feeding**
Ask your doctor or pharmacist for advice before taking/using any medicine.

**Pregnancy**
During pregnancy, you should take this medicine only if advised by your doctor. For this reason, tell your doctor if you are pregnant or become pregnant.

Growth disorders in the unborn child cannot be ruled out in long-term treatment with Decortin H during pregnancy.

If Decortin H is taken at the end of pregnancy, atrophy (shrinkage) of the adrenal cortex may occur in the newborn infant, requiring tapered replacement therapy. Prednisolone showed harmful effects on the foetus in animal trials (e.g. cleft palates). There are arguments for an increased risk of such damage in humans due to prednisolone administration during the first three months of pregnancy.

**Breast-feeding**
Prednisolone is excreted in human milk. No cases of harm in breast-fed infants have been reported to date. Nevertheless, the need for administration of Decortin H during breast-feeding should be very carefully assessed. If higher doses are needed on account of your disease, you should stop breast-feeding. Please contact your doctor immediately.
Driving and using machines
To date, there is no evidence that Decortin H impairs the ability to drive or use machines. The same applies to working without suitable safeguards.

3. HOW TO TAKE DECORTIN H

Always take Decortin H exactly as your doctor has told you.

The dose will be individually determined for you by your doctor.

Please following the dosing instructions at all times, as Decortin H may otherwise not work properly. Check with your doctor or pharmacist if you are not sure.

Method of administration
Take the tablets whole with plenty of liquid during or immediately after a meal. Hormone replacement therapy in chronic adrenocortical insufficiency is life-long.

The possibility of dosing on every other day will be checked by your doctor, depending on the clinical picture and individual response to therapy.

Unless otherwise prescribed by the doctor, the usual dose for hormone replacement therapy (beyond growing age) is:

5 to 7.5 mg prednisolone/day, divided into two single doses (morning and midday; in adrenogenital syndrome, morning and evening); if required, additional administration of a mineralocorticoid (fludrocortisone). In cases of particular physical stress, such as feverish infection, accident, surgery or childbirth, the dose should be temporarily increased as directed by your doctor.

Stressful conditions after long-term glucocorticoid therapy: up to 50 mg prednisolone/day, given in good time; then dose tapering over several days.

Treatment of certain diseases (pharmacotherapy):

For higher dosages, Decortin H is also available in tablets of 5 mg, 10 mg, 20 mg and 50 mg. Score lines allow the different individual dosages required in each case.

The following tables give an overview of the general dosing guidelines:

**Adults (dosage schedule a – d)**

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Dose in mg/day</th>
<th>Dose in mg/kg BW/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) High</td>
<td>80 – 100 (250)</td>
<td>1.0 – 3.0</td>
</tr>
<tr>
<td>b) Medium</td>
<td>40 – 80</td>
<td>0.5 – 1.0</td>
</tr>
<tr>
<td>c) Low</td>
<td>10 – 40</td>
<td>0.25 – 0.5</td>
</tr>
<tr>
<td>d) Very low</td>
<td>1.5 – 7.5 (10)</td>
<td>./.</td>
</tr>
</tbody>
</table>

  e) For disorders of the blood-forming system as part of specific regimens (see below under Dosage schedule e (DS: “e”)).

In general, the total daily dose is taken early in the morning between 6.00 and 8.00 a.m. However, depending on the disease, high daily doses can also be divided into 2 - 4 single doses and medium daily doses into 2 - 3 single doses.
Children

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Dose in mg/kg BW/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>2 - 3</td>
</tr>
<tr>
<td>Medium</td>
<td>1 - 2</td>
</tr>
<tr>
<td>Maintenance dose</td>
<td>0.25</td>
</tr>
</tbody>
</table>

In children, treatment should be administered at the lowest possible dosage. In special cases (e.g. jack-knife seizures), it is possible to deviate from this recommendation.

Dose tapering

Dose reduction starts after onset of the desired effect and in relation to the underlying disease. If the daily dose is divided into several individual doses, the evening dose is reduced first, then the midday dose, if applicable. At first, the dose is reduced in somewhat larger steps and, below approximately 30 mg/day, in smaller steps.

The duration of treatment is based on the progression of disease. As soon as a satisfactory treatment outcome is reached, the dose is reduced to a maintenance dose or discontinued. For this, your doctor will decide on a treatment schedule that you should follow exactly at all times. With monitoring of pathological activity, the following steps can serve as a guideline for dose reduction:

above 30 mg/day 10 mg reduction every 2 – 5 days,
at 30 to 15 mg/day 5 mg reduction every week,
at 15 to 10 mg/day 2.5 mg reduction every 1 – 2 weeks,
at 10 to 6 mg/day 1 mg reduction every 2 – 4 weeks,
below 6 mg/day 0.5 mg reduction every 4 – 8 weeks

High and maximum doses given over a few days can be discontinued without tapering, depending on the underlying disease and clinical response.

In patients with an underactive thyroid or liver cirrhosis, even lower dosages may be sufficient or a dose reduction may be required.

Please talk to your doctor or pharmacist if you have the impression that the effect of Decortin H is too strong or too weak.

Dosage schedule "e" (DS: "e")

In this case, prednisolone is generally administered as a single dose with no tapering required at the end of therapy. For instance, the following are recognised dosage schedules in chemotherapy:

- Non-Hodgkin’s lymphoma: CHOP regimen, prednisolone 100 mg/m², days 1 – 5; COP regimen, prednisolone 100 mg/m², days 1 – 5,
- Chronic lymphatic leukaemia: Knospe regimen, prednisolone 75/50/25 mg, days 1 – 3,
- Hodgkin’s disease: COPP-ABVD regimen, prednisolone 40 mg/m², days 1 – 14,
- Multiple myeloma: Alexanian regimen, prednisolone 2 mg/kg BW, days 1 – 4.

If you take more Decortin H than you should

In general, Decortin H is tolerated without complications even when taken in large amounts in the short term. No specific measures are required. If you notice any enhanced or unusual side effects, you should ask your doctor for advice.
If you forget to take Decortin H
You can make up for the missed dose during the day and continue taking the dose prescribed by your doctor as usual on the next day. Do not take a double dose to make up for a forgotten dose.

If you have missed several doses, the disease being treated may possibly flare up again or get worse. In such cases, you should consult your doctor, who will review the treatment and adjust it if necessary.

If you forget to take Decortin H
Always follow the dosage schedule prescribed by your doctor. Decortin H must never be stopped without consulting a doctor, as prolonged treatment with Decortin H in particular can suppress glucocorticoid production by the body. In such cases, situations of marked physical stress may be life-threatening (Addison's crisis).

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

4. POSSIBLE SIDE EFFECTS

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

Hormone replacement therapy:
Slight risk of side effects when the recommended dosages are observed.

Treatment of certain disorders at dosages higher than those in hormone replacement therapy:
The following side effects may occur, which depend greatly on the dose and duration of therapy and whose frequency can therefore not be stated here:

Infections and infestations
Masking of infections, appearance, recurrence and worsening of viral, fungal and bacterial infections, as well as parasitic or opportunistic infections, activation of dwarf threadworm infection

Blood and lymphatic system disorders
Blood count changes (increase in white blood cells or all blood cells, decrease in certain white blood cells)

Immune system disorders
Hypersensitivity reactions (e.g. drug-induced skin rash), severe anaphylactic reactions, such as heart rhythm disorders, bronchospasms (constriction of the smooth bronchial muscle), too high or too low blood pressure, circulatory collapse, heart attack, weakening of the immune system

Hormone system disorders
Development of so-called Cushing syndrome (typical signs are a large rounded face (“moon face”), obesity of the upper body and facial redness), inactivity or atrophy (shrinkage) of the adrenal cortex

Metabolism and nutrition disorders
Weight gain, increased blood sugar levels, diabetes, increased blood fat levels (blood cholesterol and triglycerides) and tissue fluid retention, potassium deficiency due to increased potassium excretion, increased appetite

Psychiatric disorders
Depression, irritability, euphoria, increased drive, psychosis, mania, hallucinations, mood swings, anxiety, sleep disorders, suicidal risk.

Nervous system disorders
Increased brain pressure, manifestation of previously undetected epilepsy and increased seizure susceptibility in cases of existing epilepsy

**Eye disorders**
Clouded lens (cataract), increased inner eye pressure (glaucoma), worsening of corneal ulcers, promotion of eye inflammation caused by viruses, bacteria or fungi

**Vascular disorders**
Increase in blood pressure, increased risk of arteriosclerosis and thrombosis, inflamed blood vessels (also as a withdrawal syndrome after long-term therapy), increased blood vessel fragility

**Gastrointestinal disorders**
Gastrointestinal ulcers, gastrointestinal bleeding, pancreatitis

**Skin and subcutaneous tissue disorders**
Stretch marks, thinning of the skin (“parchment skin”), dilated blood vessels of the skin, tendency to bruising, pinpoint or superficial bleeding of the skin, increased body hair, acne, inflammatory skin changes of the face, particularly around the mouth, nose and eyes, changes in skin pigmentation

**Musculoskeletal and connective tissue disorders**
Muscle disorders, muscle weakness, muscle atrophy (shrinkage) and osteoporosis (brittle bones) occur depending on the dose and are possible even with short-term use; other forms of bone degeneration (osteonecrosis), tendon disorders, tendon inflammation, tendon rupture and fat deposits in the spinal column (epidural lipomatosis), growth inhibition in children

Note: Complaints such as muscle and joint pain may occur if the dose is reduced too rapidly after long-term treatment.

**Reproductive system and breast disorders**
Disturbances in sexual hormone secretion (resulting in the onset of: absent periods (amenorrhoea), male patterns of body hair in women (hirsutism), impotence)

**General disorders and administration site conditions**
Delayed wound healing

**What to do**
Please talk to your doctor or pharmacist if you notice any of the side effects listed or other undesirable effects during treatment with Decortin H.

You must never stop treatment of your own accord.

If you experience gastrointestinal complaints, pain in the back, shoulder or hip joint region, psychiatric problems, noticeable fluctuations in blood sugar levels (for patients with diabetes) or any other disorders, please tell your doctor immediately.

**Reporting of side effects**
If you have any further questions, ask your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

*Bundesinstitut für Arzneimittel und Medizinprodukte*  
(Federal Institute for Drugs and Medical Devices)  
*Abt. Pharmakovigilanz*  
(Department of Pharmacovigilance)  
Kurt-Georg-Kiesinger-Allee 3  
53175 Bonn  
(website: [http://www.bfarm.de/DE/Pharmakovigilanz/form/functions/formpv-node.html](http://www.bfarm.de/DE/Pharmakovigilanz/form/functions/formpv-node.html))
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DECORTIN H

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

Storage conditions
Do not store above 25ºC.

6. FURTHER INFORMATION

What Decortin H 1 mg tablets contain
1 tablet contains 1 mg prednisolone.

The other ingredients are:
Magnesium stearate (Ph.Eur.), colloidal anhydrous silica (Ph.Eur.), sodium starch glycolate (type C, Ph.Eur.), hypromellose (Ph.Eur.), talc (Ph.Eur.), lactose monohydrate (Ph.Eur.), maize starch (Ph.Eur.), microcrystalline cellulose (Ph.Eur.).

What Decortin H 1 mg tablets look like and contents of the pack:
Decortin H 1 mg tablets are white, round tablets with a score line and marked "EM 57" on the top of the tablet. The tablet can be divided into equal halves.

Decortin H 1 mg tablets are available in packs of 20, 50 and 100 tablets.

Marketing Authorisation Holder
Merck Serono GmbH
Alsfelder Straße 17
D-64289 Darmstadt

E-mail: medizinpartner@merckserono.de

Service number (6 cents per call from the German telecom network, prices from mobile networks may vary):
tel.: +49 (0)180 222 7600
fax: +49 (0)6151 6285-816

Manufacturer
Merck KGaA & Co.
Werk Spittal
Hösslgasse 20
9800 Spittal/Drau
Austria

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Notes on dividing the tablets
Place the tablet onto a firm surface with the score line facing upwards. The tablet can be divided by pressing down on the middle of the tablet with your thumb tip (see illustration).