



Acitretin

Instructions for use

Table 1: Instructions for use (Acitretin) 1,2

Pre-treatment



- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI/Skindex-29 or -17)
- History and clinical examination should focus on musculoskeletal problems. If patient reports complaints, further imaging investigation may be performed
- Exclude pregnancy/breastfeeding: patient must be informed explicitly and extensively
 about the teratogenic risk of the medication, the necessity of effective long-term
 contraception (three years after cessation of treatment), and the possible consequences
 of becoming pregnant while taking retinoids; written documentation of this informational
 interview should be obtained
- Note that during and up to three years after treatment, blood donation is not permitted
- Laboratory parameters (see Table 2)

During treatment

- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI/Skindex-29 or -17)
- Take capsules with a meal containing some fat or with whole milk to improve absorption
- In order to prevent elevation of serum lipids and liver enzymes, alcohol abstinence and a low-fat and low-carbohydrate diet are advised.
- Preventing pregnancy is mandatory. After satisfactory contraception for at least one
 month prior to treatment, start treatment on second or third day of the menstrual cycle. .

 Double contraception is recommended (e. g., condom + pill; IUD/Nuva Ring + pill; cave: no
 low-dosed progesterone preparations/mini-pills) during and up to three years after end of
 therapy; effectiveness of oral contraceptives is reduced by acitretin





- Ask patient about spine and joint complaints at follow-up visits. If patient reports complaints, further imaging investigation may be performed
- Laboratory parameters (see Table 2)

Post-treatment

- Reliable contraception in women of child-bearing age for up to three years after therapy,
 double contraception, as described above, is recommended
- Patients may not donate blood for up to three years after the discontinuation of therapy

Recommendations for lab controls 1-3

Table 2: Recommended laboratory controls (Acitretin)

	Period in weeks			
Parameter	Pre-treatment	4	8	every 12 weeks thereafte r
Blood count*	x		х	Х
Liver enzymes**	X	x	х	
Serum creatinine	X			
Pregnancy test (urine or blood)	Х	Monthly, during treatment and up to 3 years after discontinuation (see national regulations)		
Fasting blood glucose	х			
Fasting triglycerides, cholesterol, HDL	X	x		х

Not all tests may be necessary for all patients. Patient history, risk exposure and patient characteristics have to be taken into account. Further specific testing may be required according to clinical signs, risk, and exposure.

The recommendations are based on clinical experience. No evidence is available.

¹ due to personal-financial conflict of interest 3 abstentions

^{*} Hb, Hct, leucocytes, platelets

^{**} Transaminases (AST, ALT), AP, γGT

Adverse drug reactions 4,5

<u>Please see SmPC for complete listing. The guideline subcommittee decided to comment on the</u> following aspects:

In children treated with acitretin, it is advisable to monitor growth at regular intervals.

Hypertriglyceridaemia, as defined by a fasting triglyceride level of ≥ 1.7 mmol/L, is a common adverse effect of acitretin use. Dietary and lifestyle interventions including alcohol limitation and a low-fat and low-carbohydrate diet, are effective first-line management in reducing triglyceride levels.

Dryness of skin and mucosa can be improved by moisturizing the skin and using lubricating eye drops.

It is important that patients be informed about the possibility of hair loss, as well as the reversibility of any retinoid-induced hair loss.

Special consideration during treatment ⁶

<u>Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:</u>

Surgery

There is no need to discontinue or pause acitretin use in case of elective surgery.

Important contraindications ⁷

<u>Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects.</u>

Absolute contraindications:

- Severe renal or hepatic dysfunction or hypertriglyceridemia
- As there are many other treatment options available, women of child-bearing age should generally not be treated with acitretin. Breastfeeding is also an absolute contraindication.
- Alcoholism
- Blood donation

Relative contraindications:

- Diabetes mellitus
- Hypertriglyceridemia
- History of pancreatitis

Drug interactions 8

<u>Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects.</u>

The concomitant administration of methotrexate and antifungal imidazoles could induce liver toxicity; tetracycline could induce idiopathic intracranial hypertension; lipid-lowering drugs could Increase risk of myotoxicity; low-dose progesterone pills could have insufficient contraceptive effect.

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