

Timolol for strawberry marks in babies

Information for the public
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About this information

This information explains the evidence summary about the off-label use of timolol for treating strawberry marks in babies (infantile haemangiomas). The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on [NHS Choices](#).

What are strawberry marks (infantile haemangiomas)?

Strawberry marks (infantile haemangiomas) are the most common type of birthmark, and usually appear during the first 4–6 weeks of life. They are caused by abnormal blood vessels growing in the skin or deep under the skin, or a combination of both.

Haemangiomas near the surface of the skin are usually raised, bright red areas. Deep haemangiomas may appear blue in colour. Mixed haemangiomas grow near the surface and deeper under the skin. Haemangiomas are sometimes not noticed for the first few weeks after birth, and only appear as a swelling as they grow. Haemangiomas often grow quickly in the first 3 months of life and sometimes become redder. It is unusual for them to grow after 6–10 months; at this age most haemangiomas tend to stay the same size for a while and then begin to shrink. See Great Ormond Street Hospital's information on [treating small infantile haemangiomas with topical timolol](#) for more details.

Most infantile haemangiomas do not need treatment. But they need to be looked after carefully because they can bleed if they are scratched. If treatment is needed, this may include 'off-label' steroids taken by mouth, injected or applied as a cream; 'off-label' beta-blockers taken by mouth (such as propranolol) or applied as a solution or gel directly to the surface of the haemangioma (such as timolol); laser treatment or surgery. Emollient creams (moisturisers), dressings, pain relief and antibiotics may also be needed.

About timolol

Timolol is a type of drug called a beta-blocker. Timolol is used in eye drops or gels and is licensed in the UK to reduce pressure in the eyes of people with a condition called glaucoma.

Timolol eye drops or gels are also sometimes used 'off-label' to treat infantile haemangiomas. Timolol is applied directly to the surface of the haemangioma and

probably works by reducing blood flow, which aims to make the haemangioma smaller, softer and less red.

Summary of possible benefits and harms

How well does timolol work?

Two small, higher-quality studies and several larger, lower-quality studies looked at how well timolol works for treating infantile haemangiomas, when it is applied directly to the surface of the haemangioma as a solution or gel.

In 1 higher-quality study, haemangiomas near the skin surface were slightly smaller and were less red after applying timolol gel compared with placebo (dummy) gel. In the other higher-quality study, timolol solution was better than laser treatment for treating haemangiomas near the skin surface, but mixed haemangiomas (with blood vessels near the surface and deep under the skin) improved more with laser treatment.

In a review of mostly lower-quality studies using timolol to treat mostly surface haemangiomas, about four-fifths were slightly smaller or less red after timolol treatment.

What are the possible harms or side effects?

Timolol applied directly to the surface of infantile haemangiomas is well tolerated, with few side effects reported. In the studies there was a single case of disturbed sleep in 1 baby and a single case of shortness of breath and difficulty sleeping in another.

However, it is possible that applying timolol to infantile haemangiomas could cause very rare side effects such as slow heart rate, low blood pressure, wheezing and coughing, cold fingers and toes, weakness and fatigue (seen as floppiness and lack of interest in surroundings), disturbed sleep and low blood sugar. See Great Ormond Street Hospital's information on [treating small infantile haemangiomas with topical timolol](#) for more details.

Please note that the results of research studies only indicate the benefits and harms for the population in the study. It is not possible to predict what the benefits and harms will be for an individual patient being treated with timolol.

Prescribing timolol

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council's [good practice guidelines](#). These include giving information about the treatment and discussing the possible benefits and harms so that the patient, parent or carer has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A [full version of the summary aimed at healthcare professionals](#) is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

Questions to ask

- Why is my child being offered an off-label medicine?
- What does the treatment involve?
- What are the benefits my child might get?
- How good are my child's chances of getting those benefits?
- Could having the treatment make my child feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- What may happen if my child doesn't have the treatment?

More information

NICE has published [information](#) about how evidence summaries for unlicensed and off-label medicines are developed.

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