

EFFICIENCY OF TRANSDERMAL PATCHES

2 OUT OF 3 FORMULATIONS OF AMARIN ARE MORE EFFICIENT THAN ITS RLD

“ *Transdermal patches are a solid technology and Amarin, being a trustworthy company, is going to work until they get the result.* ”
Dr. Francisco Stéfano, director of Amarin

Distinctive features

According to the WHO, a generic is a pharmaceutical product usually intended to be interchangeable with the originator brand product. At Amarin we stand out for developing more efficient generic formulations when compared to the reference product.

Our extensive know-how and broad experience in this type of project gives us the possibility of achieving developments that avoid the protection of the originator's patent. This entails enormous competitive advantages, of which we can highlight two:

- **Improved time to market:** as there is no collision to existing patents, we do not have to wait for its expiration in order to launch the generic product to the market.
- **Patentability:** in most cases our formulations, bioequivalent but different from the originator, are also patentable. Therefore, we can achieve protection on our products.

Usually, generic development is associated with the conception of equivalent substitutes for a given drug. However, at Amarin we distinguish ourselves by developing generic patches that provide superior features at the same time. Benefiting the patient, the people safety and even the environment.

Advantages of our generic patches

- **Cost reduction:** the API is the raw material with the highest incidence in the cost of the patch (between 40% and 60%). Logically, by having less load, the unitary cost is also reduced.
- **Superior efficiency:** two out of three generic patches developed by Amarin were more efficient than the original product.
- **Longer shelf life:** our formulations normally has extended duration. This is the case of Rivastigmine, Fentanyl, Methylphenidate or Selegiline, which have 50% longer shelf life than their RLD.
- **Increases treatment compliance:** due to its smaller size, it is more comfortable for the patient. At the same time, it reduces the area of the skin that is susceptible to irritation or adverse effects.
- **Better adherence:** an essential factor for the appropriate performance of the product is its adherence to the skin. Reducing the size usually improves adhesion.
- **Less drug remnant in worn patches:** especially important when it comes to opiate products, since it reduces the risk of exposure to dangerous substances.
- **Decreased environmental impact:** Due to its size, it consumes less raw materials, storage, logistics, etc. And, therefore, the associated carbon footprint.

Since 1986, at Amarin we have been developing semi-solid and transdermal products such as patches, gels and creams. While we have occasionally worked on innovative products, we mostly focus on developing of generic versions.

We have the only manufacturing plant for prescriptive transdermal patches in Latam. In addition to modern formulation and analysis laboratories, which work following **cGMP and GLP standards**. Additionally, R&D activities are carried out by a qualified team of pharmacists and chemists.

Our developments in numbers

- ✓ Two out of three Amarin developments were more efficient than the RLD
- ✓ 50% of the products have a longer shelf life than the originator
- ✓ 83% of the patches obtained at least one patent

Conclusion

Trusting the development of generic patches to Amarin team increases the chances of obtaining a superior patch compared to the reference product. Since it provides greater efficiency, lower costs and a longer shelf life of the patch.

A result that is not fortuitous but the result of the know-how that has been forged in 35 years of experience in the production of transdermal patches. Combined with a team that prints its professionalism, flexibility, transparency and commitment in each development.

“ *In Amarin, you will find a professional, serious, reliable partner backed by more than 35 years of experience for your pharmaceutical development projects.* ”

Sergio Lucero, director & CEO of Amarin