

# COVID-19 vaccination: Janssen vaccine

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## Executive summary

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Health Council of the Netherlands



The European Medicines Agency (EMA) recently issued a positive opinion concerning Janssen Pharmaceutica's Ad26.COVS vaccine against COVID-19 (brand name COVID-19 Vaccine Janssen), which has been registered by the European Commission. This means that it can be used in the Netherlands to combat the COVID-19 pandemic. The Minister of Health, Welfare and Sport has asked the Health Council of the Netherlands for advice concerning the use of this vaccine. The Committee on the Medical Aspects of COVID-19 has assessed the vaccine, based on the criteria used by the Health Council as part of the vaccination advisory process.

### **COVID-19 involves a high burden of disease**

When assessing the potential use of vaccination, the first criterion is that there must be a considerable burden of disease. That is clearly the case with COVID-19. By the start of March

2021, the Dutch Municipal Health Service (GGD) had confirmed 1,128,202 cases of disease and 15,917 deaths from COVID-19. The risk of severe morbidity increases with age, and is also greater in those with a chronic disorder.

### **The vaccine is effective**

Another criterion is that vaccination must be efficacious and effective. Vaccination involves a single dose. The Ad26.COVS vaccine's efficacy against COVID-19 has been tested in a group of over 39,000 people, half of whom received the vaccine and half a placebo. From 28 days after vaccination, the vaccine was found to have an efficacy of 66% against disease (positive PCR test in combination with symptoms) and 85% against severe disease. As yet, nothing is known about the duration of protection nor about the extent to which vaccination might prevent viral transmission.

The added value of a second dose of vaccine is also being investigated.

### **The vaccine is sufficiently safe**

The safety of vaccination is another important criterion. The Ad26.COVS vaccine is sufficiently safe and is well-tolerated. Like all medicinal products, vaccines can have adverse effects. The purpose of vaccination is to induce a response from the immune system. This is often accompanied by associated transient symptoms. Most of those who are vaccinated with the Ad26.COVS vaccine experience adverse effects. The most common adverse effects were pain at the injection site, fatigue, headache, and myalgia. These responses were more common in younger people than in older adults. In most cases, the adverse reactions resolved within two days.



**Vaccination is acceptable – the benefits outweigh the drawbacks**

In the Committee's view, the benefits of vaccination (health gains resulting from protection against COVID-19) outweigh the drawbacks (adverse effects that are usually short-lived). Thus, the criterion of acceptability has also been met. Given the current lack of data concerning the cost-effectiveness of vaccination, this aspect cannot yet be assessed.

**Recommendation: use the vaccine**

The Committee recommends the Ad26.COV2.S vaccine for use in public vaccination programmes against COVID-19, as the vaccine is efficacious, sufficiently safe, and acceptable for adults, older adults, and medical risk groups. The Committee also recommends that, the Ad26.COV2.S vaccine should be used first in older adults aged 60 and above. The sequence of vaccination should be from old to young, and vaccination should continue until everyone in this group has had an opportunity to be vaccinated. By vaccinating older adults first, severe morbidity and mortality due to COVID-19 will be avoided as much as possible.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity.

The reports are available to the public.

This publication can be downloaded from [www.healthcouncil.nl](http://www.healthcouncil.nl).

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