

Temporary deferral of COVID-19 Vaccine AstraZeneca®

Briefing- Q and A

Why has the use of AstraZeneca Vaccine been temporarily deferred?

Following a new safety alert received late on 13th March (from Norway), and pending receipt of further information from the EMA, **on a precautionary principle NIAC have recommended to temporarily defer administration of COVID-19 Vaccine AstraZeneca®. Pending further advice, the use of AstraZeneca vaccine will be temporarily deferred for the week commencing the 14th March 2021.**

The alert originated from the Norwegian Medicines Agency following four new reports of serious rare thromboembolic event, including some complicated by thrombocytopenia in younger adults after vaccination with COVID 19 Vaccine AstraZeneca.

The EMA is already investigating a number of reports of thromboembolic events from the AstraZeneca Vaccine and a report is expected over the coming days.

EMA information from 12th March was that the number of thromboembolic events in vaccinated people is no higher than the number seen in the general population. As of 10 March 2021, 30 cases of thromboembolic events had been reported among close to 5 million people vaccinated with COVID-19 Vaccine AstraZeneca® in the European Economic Area.

This vaccine along with the others, is a very important tool in our fight against COVID-19 disease.

What should I do if I have an appointment today or in the next few days to receive COVID-19 Vaccine AstraZeneca® vaccine?

You should not attend your appointment for COVID-19 Vaccine AstraZeneca® until you receive further contact from the HSE about the resumption of the programme.

You should continue to follow all COVID-19 precautions in the meantime.

Any appointments for a first or second dose of Pfizer or Moderna COVID-19 vaccine can still go ahead as they are not included in this safety alert

What about my second dose of COVID-19 Vaccine AstraZeneca® vaccine?

The recommended dose interval between the first and second dose of COVID-19 Vaccine AstraZeneca® is 12 weeks. There are no appointments scheduled for second doses at the present time. Further information will be provided about second doses as soon as it is available

What should I do if I have already received COVID-19 Vaccine AstraZeneca® vaccine?

The events are very rare and we do not know if they are caused by the vaccine. This vaccine is a very important tool in our fight against COVID-19 disease.

We know that side effects of COVID-19 Vaccine AstraZeneca® can occur within the first couple of days of the vaccine.

After the AstraZeneca COVID-19 vaccine, more than 1 in 10 people may experience:

- feeling tired

- tenderness, bruising, pain, redness or itching in the arm where they
- had the vaccine injection
- headache
- muscle pain
- joint pain
- nausea, diarrhoea or vomiting
- fever (temperature of 38 degrees Celsius or above)

More than one in 100 people may have redness or swelling where they had the injection.

It's common to develop a fever (temperature of 38 degrees Celsius or above) after any vaccination. This usually happens within 2 days (48 hours) of getting the vaccine. It usually goes away within 2 days.

If you feel uncomfortable, take paracetamol or ibuprofen following the instructions on the box or leaflet.

What if I still feel unwell more than 3 days after my vaccine?

People who have received the COVID-19 Vaccine AstraZeneca® and feel increasingly unwell **more than three days after vaccination**, and/or who notice larger or smaller blue spots in the skin (purpuric, non-blanching rash, skin haemorrhages) should consult a doctor or out-of-hours medical service.

These rare events that have been reported have usually occurred within 14 days of the vaccine.

Context

COVID-19 is a serious disease which has caused significant disease and death across the world including Ireland.

COVID-19 vaccines have been developed and authorised for use after rigorous testing and have a favourable safety profile.

More than 100 000 doses of COVID-19 Vaccine AstraZeneca® have been used in Ireland so far, mainly in Frontline healthcare workers and we can already see the significant reduction in cases of COVID-19 disease in this group after the vaccine programme.

On 12 March 2021, the National Immunisation Advisory Committee (NIAC) issued a statement regarding the COVID-19 Vaccine AstraZeneca®. The European Medicines Agency (EMA) is already investigating a number of reports of thromboembolic events following vaccination with COVID-19 Vaccine AstraZeneca®. Following a new safety alert (from Norway) received late on 13th March, and pending receipt of further information from the EMA, **on a precautionary principle NIAC have recommended to temporarily defer administration of COVID-19 Vaccine AstraZeneca®.**

Further information is expected from the EMA in the next few days, which will include a review of these additional events. This information will be reviewed by NIAC and further advice on the programme will be issued following this.