



# Coronavirus disease 2019 vaccination in patients with psoriasis: A position statement from India by SIG psoriasis (IADVL Academy)

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## Abstract

Coronavirus disease 2019 (COVID-19) pandemic has affected every sphere of life including management of psoriasis. The availability of COVID-19 vaccines has given rise to hope and at the same time some apprehensions as well. With the general population becoming eligible for vaccination, there is some confusion, on the eligibility of patients with different medical conditions and patients on immunosuppressive or immunomodulating medications for COVID-19 vaccination. Dermatologists treating psoriasis patients frequently face questions from them, whether they can undergo coronavirus disease 2019 vaccination. A PUBMED search was performed using the following strategy: 'COVID-19' AND 'Vaccine' AND 'Psoriasis'. We also performed a PUBMED search using the following strategy: 'SARS-CoV-2' AND 'Vaccine' AND 'Psoriasis'. All articles irrespective of language and publication date were included to arrive at this position statement. This position statement deals with the safety, eligibility and modifications of treatment, if needed among psoriasis patients with regards to the coronavirus disease 2019 vaccines currently available in India.

**Key words:** Coronavirus disease 2019, psoriasis, vaccine

## Introduction

Coronavirus disease 2019 (COVID-19) pandemic has affected every sphere of life and fundamentally altered the practice of medical science including management of dermatological disorders. Guidelines regarding management of psoriasis patients with reference to COVID-19 pandemic have been published.<sup>1</sup> Vaccines are possibly the most important breakthrough in the fight against COVID-19 so far. COVID-19 vaccines became available in India for the health care workers from 16<sup>th</sup> January 2021, for above 60 years

population and above 45 years with comorbidities from 1<sup>st</sup> March 2021 and for everyone above 18 years from 1<sup>st</sup> May 2021.<sup>2</sup> With this, a lot of questions arose, on the eligibility of patients with different medical conditions and patients on immunosuppressive or immunomodulating medications for COVID-19 vaccination. Dermatologists treating psoriasis patients are frequently being asked by their patients whether they can undergo COVID-19 vaccination as the vaccination effort is being ramped up in India. There are apprehensions in the mind of most patients. It thus becomes our moral duty to clarify these doubts and fear. We performed an extensive

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PUBMED search using the following strategy: ‘COVID-19’ AND ‘Vaccine’ AND ‘Psoriasis’ on 21<sup>st</sup> May 2021. All articles irrespective of language and publication date were included in the study. A total of 23 abstracts were obtained. We also performed a PUBMED search using the following strategy: ‘SARS-CoV-2’ AND ‘Vaccine’ AND ‘Psoriasis’ on 22<sup>nd</sup> May 2021. A total of 18 abstracts were obtained. Common results were excluded from the study. Further, articles for which full texts could not be accessed were excluded and we analysed 14 articles to arrive at this position statement.

### Importance of vaccination in psoriasis patients

Available data suggest that the presence of psoriasis as such does not increase the risk of COVID-19 infection or impact the disease outcome. However, the outcome tends to be poor if they have additional risk factors such as old age, metabolic disorders, obesity, chronic kidney or lung or heart disease. As it is well known that patients with psoriasis have strong association with obesity, diabetes mellitus and metabolic syndrome, it makes them vulnerable for severe COVID-19 infection.<sup>1</sup> Furthermore, psoriasis patients requiring systemic therapy are often treated with methotrexate, cyclosporine and biologicals, all of which may cause varying degrees of immunosuppression.<sup>1</sup> Both these factors place psoriasis patients at an increased risk of any infections in general, and higher risk of complications in particular, once they get infected. Vaccines induce an immune response without causing the disease and therefore decrease the chance of natural infection or at least decrease the severity of illness, if infected.

### Risk-benefit analysis of COVID-19 vaccination in psoriasis patients

For any individual, the potential benefit from vaccination has to be balanced against the possibility of vaccination-induced adverse events. Since psoriasis patients may be immunocompromised, due to comorbidities or immunosuppressive treatments, they can develop severe COVID-19 illness. Therefore, potential benefit from vaccination could be substantial. The possibility of vaccine-related adverse events following COVID-19 vaccination among psoriasis patients is expected to be same as among general population. The effect of vaccination on the clinical course of psoriasis is largely unknown. There are few initial reports of exacerbation of psoriasis after COVID-19 vaccination,<sup>3</sup> the possibility of post-vaccination flare-up of psoriasis exists and has been documented for influenza vaccination.<sup>4</sup> However, there exists the possibility that a live-attenuated vaccine, which is supposed to produce a harmless infection and immune response in an immunocompetent individual, could overwhelm the weakened immune system of a patient on immunosuppressives. The additional factor to be considered in psoriasis patients is the possibility that administration of immunosuppressive medications could be responsible for less than expected immune response to vaccination. This brings into question whether there is a need to interrupt systemic immunosuppressive medications in psoriasis patients before vaccination. If so, how much should be the time gap between cessation of therapy and vaccination? Further, the benefit of vaccination has to be weighed against the detrimental effect in psoriasis management due to interruption in treatment.

### Vaccination and psoriasis, what is known?

It is well known that live vaccines are contraindicated in patients on immunosuppressives including biologic therapy and immunosuppressives should be stopped one–three months before giving a live vaccine.<sup>2</sup> Therefore, all required vaccinations should be completed before initiation of biologic therapy, and for live vaccines, biologic therapy can be started two–four weeks after the administration of the live vaccine.<sup>5</sup>

### Mechanism of action of different types of COVID-19 vaccines

Vaccines mimic an infection, inducing an immune response without causing the disease. The mechanisms of action, approval status and availability of the COVID-19 vaccines in India are as follows [Table 1].<sup>5,6</sup>

#### Inactivated vaccine

Severe acute respiratory syndrome coronavirus 2 is killed using chemicals, heat or radiation and when injected, presents the immune system with a whole, inactivated version of the coronavirus. Example of this is Covaxin (approved in India) and Sinovac and Sinopharm (not approved in India).<sup>6,7</sup> Since the virus is killed, there is no chance of reactivation even in patients on immunosuppressives.

#### Live-attenuated vaccine

There are at present no approved vaccines in this category. This type of vaccine carries a risk of reactivation and disease in an immunocompromised individual, even though the risk is low.

#### Vaccines with protein subunit

There are at present no approved vaccines in this category. There is no risk for immunocompromised individuals as only a protein subunit is introduced in the body.

#### Vaccines with virus-like particle

There are at present no approved vaccines in this category. There is no risk for immunocompromised individuals as the complete virus is not introduced in the body.

#### Messenger ribonucleic acid vaccines

Ribonucleic acid introduced into the body codes for a severe acute respiratory syndrome coronavirus 2 protein. Here, the vaccinated person’s own cells produce a specific part of the COVID-19 virus and the immune system produces antibodies to it. Pfizer/BioNTech (not yet approved in India) and Moderna vaccines (recently approved in India) belong to this category.<sup>6,8</sup> Here, only the messenger ribonucleic acid, which only produces a viral protein, is introduced and hence is safe in the immunocompromised.

#### Deoxyribonucleic acid

Recently, Zydus Cadila’s (ZyCoV-D) COVID-19 vaccine, the world’s first deoxyribonucleic acid vaccine against COVID-19, was approved for use in India for adults and children aged 12 years and above. This is the first vaccine approved in India in the 12–18 years age group.<sup>9</sup> Here too, only the deoxyribonucleic acid is introduced which only produces a viral protein, hence is safe in the immunocompromised.

#### Replicating viral vector vaccine

There are at present no approved vaccines in this category. Here, a weakened but replicating version of a different

**Table 1: Mechanism of action of vaccines, approval and availability**

No	Mechanisms of action	Vaccines approved and available in India	Vaccines approved and available elsewhere	Risk of reactivation in immunocompromised
1.	Inactivated vaccine	Covaxin	Sinovac, Sinopharm	No
2.	Live-attenuated vaccine	-	-	Low
3.	Vaccines with protein subunit	-	-	No
4.	Vaccines with virus-like particle	-	-	No
5.	Messenger ribonucleic acid vaccines	Moderna (not yet available)	Pfizer/BioNTech	No
6.	Deoxyribonucleic acid vaccines	ZyduS Cadila's ZyCoV-D (not yet available)	-	No
7.	Replicating viral vector vaccine	-	-	Minimal
8.	Non-replicating viral vector vaccine	University of Oxford vaccine/ AstraZeneca (approved in India as CoviShield), Sputnik V vaccine, Janssen (Johnson & Johnson)(not yet available)	-	None to minimal

virus which codes for a protein of severe acute respiratory syndrome coronavirus 2 is introduced. Therefore, it carries minimal risk in immunocompromised.

#### Non-replicating viral vector vaccine<sup>6,10,11</sup>

Non-replicating engineered viruses carrying genetic code for proteins of the severe acute respiratory syndrome coronavirus 2 virus are introduced which stimulate an immune response. The university of Oxford vaccine/AstraZeneca (approved in India as CoviShield) uses genetically altered chimpanzee adenovirus. The Sputnik V vaccine (approved in India) uses two different harmless adenoviruses. Janssen (Johnson & Johnson; recently approved in India) also uses a disabled adenovirus. Here non-replicating version of a different virus which codes for a protein of severe acute respiratory syndrome coronavirus 2 is introduced so it carries none to minimal risk in the immunocompromised.

#### COVID-19 vaccines approved and available in India

1. Covaxin (a killed virus vaccine) developed by Bharat Biotech in association with the Indian Council of Medical Research<sup>7</sup>
2. The Oxford-AstraZeneca vaccine (CoviShield – a non-replicating viral vector vaccine) manufactured locally by the Serum Institute of India<sup>6</sup>
3. The Sputnik V vaccine (a non-replicating viral vector vaccine) uses two different human adenoviruses – Ad26 and Ad5 for its two vaccine doses<sup>11</sup>
4. Moderna messenger ribonucleic acid vaccine, being imported by CIPLA<sup>8</sup>
5. ZyduS Cadila's (ZyCoV-D)-ZyCoV-D was developed by Indian pharmaceutical firm ZyduS Cadila and has been approved for people aged 12 and older. This is a deoxyribonucleic acidvirus vaccine and the first one to be approved in India in the 12–18 years age group<sup>9</sup>
6. Janssen (Johnson & Johnson) manufactured by Johnson & Johnson, uses a disabled adenovirus as the non-replicating viral vector.<sup>8</sup>

#### Vaccination for psoriasis patients on systemic therapy

At present, there are no approved live-attenuated vaccines for COVID-19, hence, there is no risk of vaccine-induced severe infection in immunocompromised patients including psoriasis. Non-replicating viral vector vaccines also carry none to minimal risk in such patients. Therefore, the possibility of less than expected vaccine-induced immunity is the main

consideration for psoriasis patients on immunosuppressives as far as COVID-19 vaccination is concerned [Table 2].<sup>10,12,13</sup>

1. Patients on only topical therapy or non-immunosuppressive systemic therapies such as acitretin and apremilast<sup>14</sup> can receive any of the approved COVID-19 vaccines in India. Similarly, patients on narrowband ultraviolet B phototherapy or Psoralen ultraviolet A phototherapy can also receive COVID-19 vaccines, but general guidelines about avoiding repeated visits to health-care facilities to avoid risk of exposure to COVID-19 still apply.<sup>1</sup>
2. Patients on immunosuppressive systemic therapies: Ideally, psoriasis patients should be vaccinated before initiating on immunosuppressive systemic therapies and when the disease is well controlled and stable. However, immunosuppressive systemic therapies should not be withheld or interrupted for vaccination in a patient with active, worsening psoriasis who needs the treatment. In such patients, COVID-19 vaccination can take place while on treatment with immunosuppressive systemic therapies.
  - a. TNF-alpha inhibitors, IL-17 inhibitors, cyclosporine, mycophenolate mofetil and azathioprine: No interruption of therapy recommended for COVID-19 vaccination.<sup>10,12</sup> Specifically, secukinumab, an IL-17 inhibitor, did not suppress humoral immune response after influenza vaccination even when used in combination with other disease modifying drugs among psoriasis and psoriatic arthritis patients<sup>5</sup>.
  - b. Methotrexate and tofacitinib: In patients with well-controlled disease, these medications can be stopped for one–two weeks after vaccination. If interruption of therapy is not possible because of disease activity, COVID-19 vaccination can take place while on treatment.<sup>10,12</sup> The treating dermatologist, on his discretion, can even stop methotrexate or tofacitinib therapy temporarily before the administration of the COVID-19 vaccine, if psoriasis is well controlled or in remission.
3. Interpretation of results of immunological investigations and COVID-19 vaccination: Tuberculin skin test or an interferon release assay should be performed before or at least four weeks after the administration of a messenger ribonucleic acid-based COVID-19 vaccine. If the tuberculin skin

Table 2: Vaccination for psoriasis patients on systemic therapy

Systemic treatment for psoriasis	Safety with COVID-19 vaccines available in India at present	Any interruption in therapy needed
Acitretin	Yes	No
Apremilast	Yes	No
Narrowband ultraviolet B therapy	Yes	No
Psoralen ultraviolet A therapy	Yes	No
Cyclosporine	Yes	No
Etanercept	Yes	No
Infliximab	Yes	No
Adalimumab	Yes	No
Secukinumab	Yes	No
Methotrexate	Yes	Can be withheld for one–two weeks after vaccination, only if disease is well controlled
Mycophenolate mofetil	Yes	No
Azathioprine	Yes	No
Tofacitinib	Yes	Can be withheld for one–two weeks after vaccination, only if disease is well controlled
Systemic steroids	Yes	Consider tapering the steroid to a daily dose that is equivalent to <20 mg of prednisolone wherever possible

test or interferon release assay is performed less than four weeks after receiving a messenger ribonucleic acid-based COVID-19 vaccine, then the test should be repeated after completion of four weeks, to exclude a false-negative result.<sup>15</sup> This is important in relation to screening for latent tuberculosis before starting biologics. However, in India, tuberculin skin test and interferon release assay are not included in the diagnosis and work-up of a suspected HIV non-reactive tuberculosis patient according to National Tuberculosis Elimination Programme guidelines.<sup>16</sup>

#### Special situations

##### 4. Vaccination in psoriatic arthritis patients:

The above-mentioned recommendations with respect to non-immunosuppressive therapies like apremilast and immunosuppressive therapies such as TNF-alpha inhibitors, IL-17 inhibitors, cyclosporine, mycophenolate mofetil, azathioprine and methotrexate are applicable for psoriatic arthritis patients also. In addition, psoriatic arthritis patients on other non-immunosuppressive therapies such as hydroxychloroquine, sulfasalazine and leflunomide can receive any of the approved COVID-19 vaccines in India.<sup>12</sup> For psoriatic arthritis patients on systemic steroids consider tapering the steroid to a daily dose that is equivalent to <20mg of prednisolone wherever possible.<sup>17</sup>

##### 5. Vaccination in pregnant psoriatic patients:

Patient should be informed about the risks and benefits associated with the COVID-19 vaccines available in India. Based on the information provided, a pregnant woman may be offered any of the approved COVID-19 vaccine (Covaxin, CoviShield and Sputnik V) anytime during pregnancy.<sup>18</sup> The treatment of psoriasis should be as per the safety profile of systemic therapies for psoriasis in pregnancy and relevant guidelines. For impetigo, herpeticiformis patients on systemic steroids consider tapering the steroid to a daily dose that is equivalent to <20 mg of prednisolone wherever possible.

##### 6. Vaccination in lactating psoriasis patients:

All lactating women are eligible to receive the COVID-19 vaccines any time after delivery.<sup>18</sup> Of course, the treatment of psoriasis should be as per the safety profile of systemic therapies for psoriasis in lactating ladies and relevant guidelines.

##### 7. Vaccination in children with psoriasis:

Zydu's Cadila's (ZyCoV-D) COVID-19 deoxyribonucleic acid vaccine is approved for use in India for adults and children aged 12 years and above.<sup>9</sup> Pfizer/BioNTech vaccine has been approved by the World Health Organisation for use by people aged 12 years and above.<sup>19</sup> Although COVID-19 vaccination for children above 12 years is in progress in a few countries around the world, specific data on COVID-19 vaccination of psoriasis patients in that age group are yet to be available. Therefore, the strategy outlined for adults in Table 2 is applicable for children above 12 years as well, till more data are generated. Children (12 years and older) with psoriasis who are being treated with immunosuppressive or immunomodulating therapies such as leflunomide, methotrexate, tofacitinib and biologics are eligible for a third booster dose of messenger ribonucleic acid COVID-19 vaccine (Pfizer-BioNTech vaccine) according to the Centre for Disease Control, Atlanta. This booster dose should be administered at least 28 days following the two-dose regimen of the same vaccine.<sup>20</sup> However, Pfizer-BioNTech vaccine is yet to be approved in India.

##### 8. Immune response to COVID-19 vaccine, counselling and advice:

The immune response to any vaccination can be suboptimal for individuals on immunosuppressive medications. Similarly, in psoriasis patients on above-mentioned immunosuppressives, the COVID-19 vaccine-induced immunity may be less than that of an individual not on immunosuppressives. However, since COVID-19 illness can be life threatening, even suboptimal immunity may be helpful and a risk-benefit analysis indicates that the vaccine should still be administered at the earliest opportunity for psoriasis

patients on immunosuppressives. In this scenario, the need for continued strict adherence to hand hygiene measures, use of masks and social distancing even after vaccination becomes very important in these group of patients. Therefore, this information has to be clearly conveyed and reinforced to psoriasis patients on immunosuppressive medications scheduled for COVID-19 vaccination. Patients can consider checking antibody titres after vaccination and take additional vaccinations, if needed, to boost the level of protective antibodies.<sup>3</sup>

#### 9. Vaccine allergy:

Patients with psoriasis who are allergic to the components of a vaccine should avoid it, just like general population and other contraindications for the general public are also applicable to them.

#### 10. Vaccine interval:

Guidelines regarding the interval between two doses and interval between recovery from COVID-19 illness and first or second dose of the vaccination should be the same in psoriasis patients as for the general population.

### Conclusion

The currently available COVID-19 vaccines in India are safe to be administered to patients with psoriasis even if they are on systemic immunosuppressive agents or immune targeting therapy without altering their current treatment.

Although almost eight months have elapsed since the introduction of COVID-19 vaccination programme, there is lack of robust data to support most of the statements since the data on COVID-19 vaccination in general population itself are still emerging. Further, data on vaccination in special population groups such as psoriasis patients, pregnant psoriasis patients and children with psoriasis are scant. Hence, the above-mentioned recommendations are based on our knowledge at present and subject to revision, as new data are generated in the general population as well as psoriasis patients and as and when new vaccines become available in India, especially live-attenuated vaccines. It is important for us, IADVL members to document the change in clinical course of psoriasis in relation to COVID-19 vaccination with reference to the type of vaccine, epidemiological details, on-going treatment for psoriasis and comorbidities. This can generate valuable data in a comparatively short period of time in a populous country like ours with a robust COVID-19 vaccination programme.

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### Conflicts of interest

There are no conflicts of interest.

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