The situation and scientific knowledge on possible treatments for COVID-19 are evolving every day and, in order to ensure the proper use of available medicines, it is imperative to follow the recommendations issued by the Health Authorities in this domain.

In August 2020, the European Medicines Agency (EMA) authorised a first treatment for COVID-19 patients with pneumonia requiring respiratory assistance. The medicine is called VEKLURY® and its active substance is remdesivir. This medicine is administered intravenously. For more information, please see the FAQs.

Regarding other drugs potentially effective in the treatment of COVID-19 infection, their use must primarily take place within the framework of ongoing clinical trials or on the basis of specific authorisations issued by the Health Directorate. Their use for COVID-19 is outside the scope of the existing marketing authorisation (Autorisation de mise sur le marché - AMM) and close monitoring is necessary in order to assess their benefits and risks.

Under no circumstances should the medicines listed below be used in self-medication, on prescription from a local physician or self-prescription by a physician for himself or herself, for the treatment of COVID-19.

The Health Directorate thus calls on everyone to take responsibility in order to avoid unnecessary hospitalisations resulting from the misuse of medicine and to enable caregivers to take care of COVID-19 patients in the best possible conditions.

The Pharmacy and Medicines Division closely monitors adverse reaction cases reported under COVID-19 and reminds healthcare professionals of their duty to report adverse reactions suspected of being related to a drug regardless of its conditions of use.

For more details, click here.

It is also recalled that as part of clinical trials, promoters are required to report suspected unexpected serious adverse reactions (SUSAR) related to a medicinal product via Eudravigilance (EVCTM module). For more details, click here.

2. SUSAR – Suspected Unexpected Serious Adverse reaction
3. EVCTM – Eudravigilance Clinical Trial Module
FAQ

The information contained on this site is regularly updated. However, never stop a treatment in progress without asking your physician for advice, as this may expose you to a worsening of your condition.

If you have asked a question and you can not find the answer in the list below, either your question already exists in another wording, and is therefore already published, or your question is too specific, or is a medical decision. We cannot therefore answer you individually or substitute for your physician’s decision. In this case, please contact your general practitioner or specialist.

01. MEDICINE FOR THE TREATMENT OF COVID-19 INFECTION

Medicinal products must be prescribed and used in accordance with a marketing authorisation with due regard to the warnings and other information provided in the Summary of Product Characteristics (SmPC) and package leaflet. If the drug has not yet been authorised for the treatment of COVID-19, they must be prescribed in accordance with clinical judgement as well as guidelines issued by the World Health Organisation (WHO) and relevant national and international bodies.

What medicines are currently being used to treat COVID-19?

Scientific knowledge about possible treatments is evolving every day. However, only one drug has so far been shown to be effective in the treatment of COVID-19 infection, namely VEKLURY® (remdesivir) 4.

At the moment, the most studied medicines are antimalarial and some antiviral medicines. Among the potential treatments for COVID-19 disease, those that are in a more advanced state of development are:

- Remdesivir (VEKLURY®, a product that already has a marketing authorisation but is still being studied in clinical trials)
- The European Medicines Agency (EMA) has published information on the conditions of use of remdesivir in the treatment of COVID-19 infection 5.
- Dexamethasone, a corticosteroid medicine, which appears to decrease mortality in patients receiving invasive mechanical ventilation or only oxygen. However, no efficacy has been observed for patients who do not require respiratory assistance 6 7.
- Systemic interferons and in particular interferon beta (authorised for the treatment of diseases such as multiple sclerosis).
- Monoclonal antibodies with action on components of the immune system.

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The following medicines did not demonstrate therapeutic efficacy in the large-scale clinical trial “Discovery” and are therefore no longer being studied:

- Lopinavir/ritonavir (known as Kaletra® and authorised for the treatment of HIV infection).
- Chloroquine and hydroxychloroquine (authorised for the treatment of malaria and certain autoimmune diseases such as lupus or rheumatoid arthritis).

Tocilizumab (ACTEMRA®/ROACTEMRA®) has shown no improvement in the clinical status of patients with COVID-19-associated pneumonia and no reduction in patient mortality (COVACTA trial).

In Luxembourg, the Conseil supérieur des maladies infectieuses (CSMI) has issued recommendations for the management of patients with a confirmed or suspected COVID-19 infection 8.

Which patients to treat?

Only seriously ill and hospitalised patients can be treated with the medicines listed above. Indeed, there is insufficient scientific evidence on the efficacy but also on the risks of these medicines in the treatment of COVID-19 and a good medical follow-up is necessary to ensure the patient’s safety.

These medicines are therefore not recommended for patients with mild symptoms or for preventive use because the risks are considered too great in relation to the benefits.

For patients who are not hospitalised, treatment aims to relieve symptoms. Paracetamol remains the first choice to relieve fever and pain. A cough syrup may also be prescribed.

Are there any risks associated with the use of these medicines?

These medicines are already being used to treat other very serious diseases and for which adverse effects, sometimes serious, are known. These medicines may also interact with other medicines.

The risks of the new use of these existing medicines for COVID-19 are little known at this time. It should be used with great caution.

How to use existing medicines for a new disease such as COVID-19?

In some situations, even if a medicine has not yet been authorised to be placed on the market, it may still be used for a new disease. This is the case for some medicines currently being studied to treat COVID-19 disease.

Several possibilities:

• CLINICAL TRIALS

Clinical trials are scientific research conducted on humans. Trials with (potential) medicines are based on the most advanced scientific developments before they are made available to the general public. In some cases, thanks to clinical trials, the people tested can have access to innovative treatments before they are even put on the market.

• COMPASSIONATE USE OR MEDICAL NEED PROGRAMME

Emergency medical programmes or compassionate use may be used when a patient or group of patients with a chronic, severely disabling or life-threatening condition cannot be treated satisfactorily with other medicines.

• OFF-LABEL USE

These are medicines used for purposes other than those specified in the package leaflet (e.g. a different condition, dosage or patient group). They are therefore uses for which the medicinal product is not authorised. Doctors have the therapeutic freedom to prescribe off-label medicines. However, they must carefully consider this use, particularly on the basis of scientific evidence and potential risks. Physicians must inform the patient in advance of the off-label use and of any associated risks. Off-label use is not recommended as no statistically relevant clinical data is generated.

What do I need to know about hydroxychloroquine?

Hydroxychloroquine has not been shown to be effective in ongoing clinical trials. It is an old molecule, used as an antimalarial. Hydroxychloroquine, marketed in Luxembourg under the name PLAQUENIL®, is a chloroquine derivative, currently effective in and authorised for the treatment of malaria and certain autoimmune diseases such as lupus or rheumatoid arthritis.
What are the risks associated with hydroxychloroquine?

Both chloroquine and hydroxychloroquine can have serious side effects, especially at high doses or when combined with other medicines, even long after the treatment has ended.

The most common risk is cardiac toxicity. Other risks, such as severe allergies, eye, muscle, neurological or psychiatric disorders, are reported. It is also important to know that this medicine can aggravate certain existing diseases and interact with many medicinal products.

The risks associated with the new use of this medicine for COVID-19 are very little known at this time and are in addition to the known risks described above. Under no circumstances should they be used as self-medication, on prescription from a local physician or self-prescription by a physician for himself or herself, for the treatment of COVID-19.

Recent studies (9,10) have reported serious (QT prolongation) or even fatal heart rhythm disorders with chloroquine or hydroxychloroquine, especially when the medication is taken in high doses or in combination with the antibiotic azithromycin.

Hydroxychloroquine: What should patients do?

• Do not take these medicines on your own.

• If you have any questions about the use of chloroquine or hydroxychloroquine or any other medicine, ask your physician or pharmacist.

• Use chloroquine or hydroxychloroquine only if it has been prescribed for you and if a physician supervises your treatment.

• A lot of falsified medicinal products against COVID-19 are illegally available for purchase on the internet. Do not buy them.

What do I need to know about VEKLURY® (remdesivir)?

VEKLURY® (remdesivir) has been approved in Europe for the inpatient treatment of COVID-19-related pneumonia requiring oxygen therapy in adults, the elderly and adolescents over 12 years of age with a weight of at least 40 kilos.

The main side effects, which can lead to the discontinuation of treatment, are allergic reactions and an increase in liver enzymes. In addition, in laboratory animals, remdesivir has shown the possibility of severe impairment of renal function.

Other relatively common side effects are headaches and nausea.

It is not recommended to administer it to pregnant women, as there is insufficient information to date to assess the risks of administration to the mother or fetus. Nevertheless, when the clinical condition of a patient infected with COVID-19 warrants it, it may be administered.


What do I need to know about KALETRA® (lopinavir/ritonavir)?

KALETRA® (lopinavir/ritonavir) is a medicine used in the treatment of HIV infection (human immunodeficiency virus). Its effectiveness in the treatment of COVID-19 infection has not been proven. Its use is also associated with numerous adverse effects and interactions with other medicines. Therefore, an increased medical follow-up of these patients is necessary.

What do I need to know about ROACTEMRA® (tocilizumab)?

ROACTEMRA® is a medicine used to treat adults with severe rheumatoid arthritis and children from 1 year of age with juvenile idiopathic polyarthritis (without known cause) in whom other treatments have not worked well enough.

This medicine is also being evaluated for the treatment of severe episodes of cytokine release syndrome, also known as "cytokine shock", which can occur in patients with severe COVID-19. However, well-known side effects include upper respiratory tract infections (nose and throat infection), nasopharyngitis (inflammation of the nose and throat), headache, hypertension (high blood pressure) and abnormal liver function tests. For these reasons, this medicine should be used with caution in patients with a history of recurring or long-term infections, or in patients with other diseases that could increase the risk of infections, such as diabetes.

What do I need to know about dexamethasone?

Dexamethasone is a medicine used for the treatment of various autoimmune and inflammatory diseases. It is also administered to cancer patients undergoing chemotherapy to control certain side effects of their anti-tumour treatment. Preliminary observations suggest a positive role for this medicine in the treatment of patients with severe COVID-19 pneumonia, in combination with other medicines currently in use.

However, Dexamethasone has some common side effects (affecting more than one in ten people) including hyperglycemia (high blood sugar levels), insomnia, muscle pain and weakness, tiredness or weight increase.

02. MEDICINE FOR THE TREATMENT OF OTHER DISEASES 
(IN PATIENTS WITH OR AT RISK OF A COVID-19 INFECTION)

Patients who are already taking medicines that were prescribed to them before the onset of COVID-19 should not discontinue their treatment, especially if it is being used for the management of a chronic condition. If patients have any concerns, they should talk to their physician or pharmacist.

Medicines should be prescribed and used in accordance with clinical judgment, with due regard to the warnings and other information provided in the Summary of Product Characteristics (SmPC) and package leaflet, as well as guidelines issued by the WHO and relevant national and international bodies.

In the FAQs, tips are available concerning:

- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen;
- Angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs, or sartan medicines).

A. Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen
B. Angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs, or sartan medicines)
C. Anti-inflammatory steroids, or corticosteroids
D. Vaccines
E. Antiasthmatic medicines
F. Antihistamines (antiallergic medicines)
G. Immunosuppressive agents
H. Medicines for diseases of the heart and blood vessels
I. Medicines for chronic inflammatory diseases

At this stage, it is not possible to provide advice on the safety of many other medicines in patients with or at risk of a COVID-19 infection.

Indeed, there is insufficient clinical or epidemiological data and the understanding of the new virus and its interactions with the body’s natural defences is still incomplete. Observational data, if not carefully collected and analysed, can be misleading.

When prescribing or administering medicines to patients with COVID-19, healthcare professionals should exercise clinical judgment while keeping in mind:

- The benefits and risks of the medicinal product, as described in the product information (package leaflet), including warnings;
- National treatment directives
- Any relevant guidelines issued by the European Medicines Agency (EMA 12) and the World Health Organization (WHO 13)

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13. https://www.who.int/
A. Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen

When starting treatment for fever or pain in patients with COVID-19, patients and health care professionals should consider all available treatment options, including paracetamol and NSAIDs. Each medicine has its own benefits and risks that are included in the product information and should be considered in conjunction with national EU treatment guidelines, most of which recommend paracetamol as the first treatment option for fever or pain.

In accordance with EU national treatment guidelines, patients and healthcare professionals may continue to use NSAIDs (i.e. ibuprofen) in accordance with the approved product information (package leaflet). Current advice includes that this medication should be used at the lowest effective dose for the shortest possible time.

Patients who have questions should talk to their physician or pharmacist. There is currently no reason for patients taking ibuprofen to discontinue treatment based on the above. This is especially important for patients taking ibuprofen or other NSAIDs for chronic conditions.

See: sante.lu ou cette circulaire est disponible (Circ. 12.20 DPM)

B. Angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs, or sartan medicines)

Angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs, or sartan medicines) are most commonly used to treat patients with hypertension, heart or renal disease (e.g. valsartan or irbesartan).

There is currently no evidence from clinical or epidemiological studies linking ACE inhibitors or ARBs to worsening of COVID-19 infections.

It is therefore strongly discouraged to interrupt treatment with ACE inhibitors or sartans, as the risk of interruption is too high, especially for patients with heart failure.

C. Anti-inflammatory steroids, or corticosteroids

Non-steroidal anti-inflammatory drugs (NSAIDs) are medicines used for fever, pain and/or for their anti-inflammatory properties (e.g. aspirin, ibuprofen, ketoprofen, diclofenac, ...). The term "non-steroidal" distinguishes them from corticosteroids (cortisone and derivatives, e.g. dexamethasone, hydrocortisone, prednisone, methylprednisolone, ...), which also have anti-inflammatory effects and many other properties. Be careful, paracetamol is not an NSAID.

These medicines, which you take chronically to treat autoimmune (renal, ...) or inflammatory (rheumatic, ...) diseases, must not be stopped on your own initiative.

Any unjustified discontinuation of treatment could lead to a relapse of your disease and complicate your medical management in the current context. Given your fragility, it is essential to adopt the recommended preventive measures (protective measures and confinement at home as much as possible). In the event of signs suggestive of infection (fever, cough, aches and pains, etc.), contact your physician or the referring physician for your condition.
As for the use of **intra-articular injections**, given the risks of infection, it is preferable during the pandemic to limit the use to emergency injections.

As far as **creams or ointments** are concerned, there is currently no data suggesting that corticosteroids administered topically increase the risk of infection, severity or duration of COVID-19 infection. On the other hand, discontinuing treatment puts you at risk of a resurgence of your skin condition. Nevertheless, it is recommended that elderly people receiving high doses of topical steroids (dermocorticoids) contact their general practitioner or dermatologist.

With regard to nasal or ocular administration, there is currently no data suggesting that corticosteroids used topically increase the risk of infection, severity or duration of COVID-19 infection. On the other hand, discontinuing treatment puts you at risk of a resurgence of your condition.

For use in **asthma exacerbation**, corticosteroids administration should not be delayed, even with suspicion of COVID-19 infection. Contact your physician to confirm dosage regimen and duration of treatment in case of COVID-19 infection.

Reference: Société de Pneumologie de Langue Française (SPLF) 14

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**D. Vaccines**

Vaccination is not contraindicated during this epidemic. At present, child vaccination programmes are continuing without any change in the vaccination schedule for vaccinations up to 2 years of age. Indeed, the coronavirus epidemic should not hinder the normal care of children. The collateral damage potentially induced by the absence of vaccination could be more detrimental than COVID-19 itself, as other infectious diseases do not cease during this period. Thus, consultations in the first month of life and those involving recommended vaccinations should be continued. Other non-emergency consultations, with or without vaccinations, should be postponed.

In order to protect your child from being contaminated by COVID-19, make sure to respect the protective measures.

Bear in mind that the flu vaccination does not protect against coronavirus. There is currently no vaccine against the coronavirus.

Reference: WHO 15, Luxembourg Ministry of Health 16

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**E. Antiasthmatic medicines**

Whether it’s fluticasone, salmeterol, montelukast, inhaled corticosteroids - the priority is asthma control. A viral infection can put you at risk of an acute asthma attack that can be fatal. It is therefore imperative not to stop or reduce a background therapy in order to avoid hospitalisation for this asthma. Observe the prescription for your continued treatment strictly and more than ever, and if in doubt, consult your physician.

Reference:

Regarding inhalers, you must be the only one to use your inhaler. It must be clean and kept in a place where only you have access. This way, your inhaler will not be contaminated. You do not need to change it. These measures also apply to spacer devices, where the level of alertness is all the more important and warrants regular washing with soap and water.

Reference: Société de Pneumologie de Langue Française (SPLF) 17,18

F. Antihistamines (antiallergic medicines)

Antihistamines (e.g. cetirizine, levocetirizine, loratadine, rupatadine, ...) block the histamine receptors whose stimulation causes allergy symptoms. By blocking these receptors, cetirizine and other antihistamines do not decrease defences against viruses and bacteria. There is therefore, a priori, no risk in taking antihistamines during this period. In addition, if the signs of rhinorrhea (runny nose) are important, it may be helpful to take antihistamines rather than another treatment, in order to differentiate between respiratory signs of potential infection 19.

G. Immunosuppressive agents

If you are undergoing immunosuppressive treatment, for example after undergoing an organ transplant or preparing to receive one, or if you suffer from an autoimmune disease (e.g. lupus, scleroderma, rheumatoid arthritis, Crohn’s disease, ulcerative colitis, ...), you should not stop your treatment. This would put you at risk of rejection of your transplant. Observe protective measures scrupulously.

If symptoms suggestive of an infectious episode occur, contact your physician with a reminder of your treatment.

H. Medicines for diseases of the heart and blood vessels

If you are being treated for cardiovascular disease, hypertension or other conditions, for example with beta-blockers (drugs with names ending in -olol, such as propranolol), calcium channel blockers (drugs with names ending in -dipine, such as amlodipine) or diuretics (such as bumetanide, furosemide, piretanide, amiloride, spironalactone, eplerenone, cicletanine, hydrochlorothiazide, indapamide), you must not stop your treatment. This would put you at risk of having your arterial hypertension rebound or poor control of your heart failure or cardiovascular disease.

To date, there is no signal for an increased risk of contracting coronavirus with these medicines.

Specify your usual medicines if a physician should prescribe a new medicine (e.g. antibiotic treatment, anticoagulant...).
If you are being treated with an anticoagulant by oral administration (Xarelto®, Pradaxa®, Eliquis®, Coumadine, Sintrom®, Previscan®...) or by injection (Heparin, Lovenox®, Arixtra®, Calciparine, Innohe...) for a heart rhythm disorder, phlebitis, or pulmonary embolism, or following surgery, or for cardiovascular prevention, you must not stop your treatment. This would expose you to the risk of thromboembolic events occurring or recurring.

If you are being treated for a heart rhythm disorder with Cordarone, Flecaine, Diltiazem, Verapamil®, or others, you should not stop your treatment during the epidemic. This would put you at risk of having a recurrence of your heart arrhythmia.

There is no data to support a link between anti-arrhythmic agents and the risk of infection or severity of COVID-19.

I. Medicines for chronic inflammatory diseases

If you are being treated for a chronic inflammatory disease (Crohn's disease, rheumatoid arthritis or others), in general, you should continue the treatment of your condition. Any suspension would expose you to a flare-up of your inflammatory disease and thus to an episode of fragility. This also applies if you are taking an aminosalicylate medicinal product (such as mesalazine).

Aminosalicylates exert a direct local anti-inflammatory action on the mucous membranes of the small intestine and colon. They are not related to cortisone drugs. They are also different from aspirin or other conventional non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, which are used for fever or pain.

Although the mechanism of action of mesalazine is not fully elucidated, there are currently no data suggesting that aminosalicylates increase the risk of infection, severity or duration of COVID-19 infection.

03. INFORMATION FOR PREGNANT WOMEN

A. Use of hydroalcoholic products

The French Society for Hospital Hygiene considers that the risk linked to the passage of alcohol into the organism is negligible and authorises the use of hydroalcoholic products (HAP) (gels and solutions) during pregnancy, on dry hands and recommends rubbing until the product has completely evaporated.

In general, friction disinfection with HAP is the reference technique in all hand hygiene indications in the absence of visible soiling.

In the case of visibly soiled hands, simple hand washing with mild soap and water is recommended. Privilege liquid soap. Respect a minimal cleaning duration of thirty seconds, rinse your hands thoroughly and dry them well with a clean cloth or towel.

04. INFORMATION FOR BREASTFEEDING WOMEN

Breastfeeding is not contraindicated in the context of the coronavirus epidemic. Indeed, the first available data indicate that the virus does not appear to be excreted in the milk. Thus, breastfeeding is recommended for women who wish to do so, in the same way as under normal circumstances. Furthermore, to protect you and your child, protective measures must be respected 21.

05. INFORMATION CONCERNING CHILDREN

A. Use of hydroalcoholic products for disinfection

The use of hydroalcoholic gels is widespread. Their safety of use was evaluated following the H1N1 influenza epidemic, with no reports of toxicity on healthy skin, and they are considered well tolerated, including in children 22. However, hand washing is recommended as a first line of action as soon as a drinking water source is available, using soap (liquid soaps are to be preferred).

Respect a minimal cleaning duration of thirty seconds, rinse your hands thoroughly and dry them well with a clean cloth or towel. If a water source is unavailable, wash the hands with hydroalcoholic gel while following these recommendations:

- Keep the child from bringing their hands to their mouth after application and wash them with soap as soon as possible.
- Keep gel solutions out of the reach of small children (either for the risk of ingestion or splashing in the eyes).

22. https://www.ansm.sante.fr/var/ansm_site/storage/original/application/3c6ccceaa290f8d00e649160cd5d4a9aa.pdf
B. Vaccinations

Vaccination is not contraindicated during this epidemic. At present, child vaccination programmes are continuing without any change in the vaccination schedule for mandatory vaccinations. Indeed, the coronavirus epidemic should not hinder the normal care of children. The collateral damage potentially induced by the absence of vaccination could be more detrimental than COVID-19 itself, as other infectious diseases do not cease during this period.

Thus, consultations in the first month of life and those involving highly recommended vaccinations must be maintained at least until the age of 2 years. Other visits, with or without vaccinations, should be postponed.

In order to protect your child from being contaminated with the coronavirus, make sure to respect the protective measures.

C. Ongoing treatments

It is recommended that you do not stop ongoing treatments without first consulting your general practitioner or specialist, otherwise you run the risk of aggravating your current illness.

06. PUTTING AN END TO PRECONCEIVED IDEAS

The World Health Organization (WHO) has published a list of preconceived ideas which have turned out to be false. This list, in English, is available here: